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PRINCIPAL INVESTIGATOR: Ronald E. Myers, Ph.D.

CONTRACTING ORGANIZATION: Thomas Jefferson University
Philadelphia, PA 19107

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13. ABSTRACT (Maximum 200 Words) This report describes a randomized trial of an intervention designed to facilitate informed decision-making about prostate cancer screening. The study population included 199 adult men in the patient population of a university-based internal medicine practice. Participants completed a baseline survey and were randomly assigned to either a Standard Intervention (SI) Group (n=99) or an Enhanced Intervention (EI) Group (n=100). Men in both groups were mailed a prostate cancer informational booklet. The EI Group was also offered a decision counseling session to clarify personal preferences about screening. Six months later, a medical chart audit was performed. Screening utilization was defined in two ways. The primary outcome defined utilization as having both a digital rectal exam (DRE) and a prostate specific antigen (PSA) test. The secondary outcome was defined less strictly to reflect common practice among physicians. It regarded a PSA test, with or without a DRE, as screening. For the primary outcome, the EI Group had lower screening rates than the SI Group (8% vs. 12%). For the secondary outcome, the rates were similar (18.0% vs. 18.2% respectively). Neither of these effects was statistically significant. Results of multivariable analyses showed that race was a significant predictor of the secondary outcome (p=0.012).				
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Introduction

On October 1, 1998, Thomas Jefferson University received a grant from the United States Army Medical Research and Material Command that supported development and testing of a theory-based decision counseling intervention to facilitate value-based decision making about having a prostate cancer screening examination. The study had three specific aims: (1) develop the intervention, (2) implement the intervention and measure its impact on screening utilization, and (3) assess the effect of the intervention on the knowledge, attitudes, beliefs, and behaviors of participants related to prostate cancer and screening.

These objectives were accomplished by

- Designing the educational booklet and the counseling session
- Pre-testing the intervention
- Training the health-educator
- Recruiting study participants from a large primary care practice
- Administering a baseline survey to study participants
- Assigning participants randomly to either a standard intervention or an enhanced intervention group
- Delivering the interventions
- Administering an endpoint survey
- Completing a medical chart audit to document outcomes
- Analyzing data to assess study outcomes

Body

Background

In the absence of definitive results of clinical trials assessing whether detecting and treating early prostate cancer has an impact on mortality, expert opinion on the subject of prostate cancer screening currently is divided. The American Urological Association [1] and the American Cancer Society [2, 3] recommend that

- Men who are 50 or more years of age and have a life expectancy of 10 or more years should be offered a digital rectal examination (DRE) and a prostate specific antigen (PSA) test on an annual basis
- Screening should be considered at an earlier age for men less than 50 years who are at high risk (i.e., African American men and men with a family history of prostate cancer).

Proponents of screening point out that combined DRE and PSA testing is effective at identifying men with early prostate cancer. In addition, they cite evidence that men who are diagnosed with localized prostate cancer and are treated aggressively have higher survival rates as compared to men who are diagnosed with late stage disease [4, 5].

In contrast, guidelines put forward by the United States Preventive Services Taskforce and the Canadian Task Force on Preventive Health Care do not support routine prostate cancer screening [6, 7]. The American College of Physicians has also recommended against prostate cancer screening among older adult men and has suggested that if screening is performed, men should be advised in advance about the potential benefits and harms of prostate cancer early detection [8]. Skeptics of screening argue that there have been no randomized trials that have demonstrated a reduction in mortality as a result of prostate cancer screening [9, 10], and that studies

evaluating the benefits of early prostate cancer detection are flawed because they do not monitor individuals with negative screening tests over time to ensure that they do not subsequently develop prostate cancer [11].

In addition, aggressive treatment for early-stage prostate cancer can cause serious adverse outcomes (e.g., impotence, incontinence, stricture, bowel injury, and even death) [12, 13]. It is imperative that men know about the uncertainties surrounding prostate cancer screening before they decide on a course of action.

At the same time, individuals are being asked to assume an increasing level of responsibility for decision-making about personal health care. Patients are now expected to act as partners with health care professionals to engage in shared decision making about health-related issues. This shared decision-making paradigm is an ideal that is supplanting the more traditional model in which the medical practitioner assumes responsibility for choosing a health care strategy that is in the best interests of the patient. To facilitate shared decision making, it is important to provide information that is needed to make informed decisions, enable patients to recognize the importance and legitimacy of their role in medical decision making, understand the implications of choosing from among different health care alternatives, and consider their personal values and preferences related to the choices at hand.

Intervention Development

Intervention Components

The intervention consisted of a prostate cancer informational booklet and a counseling session with a health educator. The informational booklet, *Is Being Checked for Prostate Cancer a Good Idea or Bad Idea?* was based on epidemiological and clinical information about prostate cancer and early detection. It described the prostate gland and its function; described risk factors for and symptoms of prostate cancer; explained early detection screening; discussed the pros and cons of screening and options for early and late prostate cancer treatment.

The research team also developed a counseling protocol that was designed to help participants to clarify their preference concerning whether or not to have a prostate cancer-screening exam. The protocol focused on identifying factors that might affect the individual's preference (decision factors) and by generating a decision preference score based on the most salient decision factors.

Pre-testing the Intervention

A draft version of a prostate cancer screening informational booklet was first reviewed for accuracy by clinicians in the Department of Urology of Thomas Jefferson University. We then field-tested the booklet in face-to-face interviews. A health literacy consultant from the Health Promotion Council of Southeastern Pennsylvania conducted focused interviews with 20 age-eligible male patients from the Jefferson Internal Medicine Associates (JIMA) patient population. The goal of the interviews was to determine whether the men could recognize the purpose of the informational booklet and to ascertain that they understood the language, terminology, and concepts contained in each component. Most men reported that the text was easy to read and interesting. However, it was suggested that the medical terminology should be simplified and more pictures should be included. Many men said that they thought the purpose of the booklet was to encourage prostate cancer screening. Many disregarded a central message in the booklet, that is, there is a decision to be made about screening. The interviewees also indicated that they would be likely to read the booklet and consider the issue of screening more carefully if they were encouraged to do so by their physician. We modified the educational booklet to address each of these concerns. Men who participated in the interviews were excluded from further participation in the study.

A health educator and a volunteer client recruited from the community made a videotape of a mock decision counseling session. The video was shown to two focus groups of age-eligible men from two community-based primary care physician practices. There were six men in the first group and eight in the second. After viewing the videotape, focus group participants suggested that the informational booklet be made available before the decision counseling session to provide basic education about prostate cancer and screening. In addition, the men suggested that the process of eliciting screening decision factors should be simple and direct. They also

recommended that the steps involved in computing a decision score, which was done manually with pencil and paper in the videotape, be automated. Finally, the men suggested that the screening preference score results should be displayed visually and that a written copy should be provided to the patient. These suggestions all were incorporated into the final version of the decision counseling protocol.

According to the final protocol, a health educator meets with the patient and initially reviews the format and content of the booklet. The health educator then prompts the patient to identify decision factors by asking him to complete the following sentences: "I would want to have a prostate screening examination because..." and "I wouldn't want to have a prostate cancer screening examination because..." Each participant was then asked to identify and rank the three most important factors and to make pair-wise comparisons of the relative importance of those three factors. Following Analytical Hierarchy Process (AHP) methods, the health educator guided the men to assign values to the decision factors and used assigned values to calculate the participant's screening preference score, using a programmable hand-held calculator. The health educator shares this information with the participant and verifies that the interpreted score is consistent with the individual's position relative to screening (i.e., wants to screen, undecided, does not want to screen). If the findings are inconsistent, the health educator reviews identified decision factors and their weights to resolve any discrepancies, computes the screening preference score again, and validates the results. Finally, a screening decision is elicited.

Intervention Implementation

Study Population

The study population was drawn from a sampling frame of 1,703 men, aged 50 to 69 years who were in the patient population of Jefferson Internal Medicine Associates (JIMA) in Philadelphia. A total of 550 men were randomly selected from this sampling frame as potential study participants. By reviewing patient medical charts and my making initial telephone contacts to verify eligibility, 221 men were found to be ineligible because they had a personal history of prostate cancer or benign prostate hyperplasia, or had had a prostate biopsy or a transrectal ultrasound procedure. A total of 329 men remained in the sampling frame.

Baseline Survey

A Baseline Survey questionnaire was developed for administration to the men in the remaining study sample. The instrument included items that served to make operational constructs defined in the Preventive Health Model, which identifies three sets of factors that influence patient decision-making—cognitive, affective, and social influences. Items were included in the survey instrument to measure personal background factors (i.e., socio-demographic characteristics and prostate cancer screening history). In addition, single items were included to measure knowledge about prostate cancer and screening (two single items), self-efficacy (one item), and social support and influence related to screening (two single items). The survey also included items that formed a cognitive scale (i.e., perceived salience and coherence of screening (eight items, Cronbach's $\alpha=0.67$)), two affective scales (i.e., fear of being diagnosed with prostate cancer (three items, $\alpha=0.63$) and concern about screening-related risks and benefits (seven items, $\alpha=0.62$)), and an intention scale (i.e., intention to have a screening examination (four items, $\alpha=0.89$)).

Demographic Characteristics of Study Participants

We used both telephone and mail approaches to administer the Baseline Survey to 199 (60%) men. Among responders, 103 men completed the survey by telephone, and 96 completed the survey by mail. The 130 (40%) non-responders were either unavailable for contact during the survey field period or declined to participate. Baseline Survey respondents were randomly assigned either to a Standard Intervention (SI) Group (N=99) or an Enhanced Intervention (EI) Group (N=100).

As shown in **Table 1**, most study participants were less than 60 years old, were married, had attended some college, and had been born outside of Philadelphia. Nine percent of the men reported a family history of prostate cancer. Forty-four percent of the men reported having prostate cancer screening (that is, a digital rectal exam

(DRE) and a prostate specific antigen (PSA) test) in the previous year. There were no statistically significant differences between the two study groups.

Table 1. Demographic Characteristics of Study Participants

Characteristic		Total		Enhanced Intervention		Standard Intervention		p< **
		n*	%	n	%	n	%	
Age								0.644
	50-59 years	140	70.4	72	72.0	68	68.7	
	60-69 years	59	29.6	28	28.0	31	31.3	
Race/ethnicity								0.511
	Non-White	48	24.1	22	22.0	26	26.0	
	White	151	75.9	73	73.7	78	78.0	
Marital Status								1.000
	Married	144	72.7	73	73.0	71	72.4	
	Unmarried	54	27.3	27	27.0	27	27.6	
Education								0.219
	≤ 12 years	60	30.2	26	26.0.0	34	34.3	
	> 12 years	139	69.8	74	74.0	65	65.7	
Birthplace								0.322
	Philadelphia	90	45.5	49	49.0	41	41.8	
	Outside Philadelphia	108	54.5	51	51.0	57	58.2	
Family history of prostate cancer								0.081
	Yes	18	9.0	13	13.0	5	5.0	
	No	181	91.0	87	87.0	94	95.0	
PSA + DRE in past year								0.154
	Yes	87	43.7	49	49.0	38	38.4	
	No	112	56.3	51	51.0	61	61.6	

* Counts may not add to full study sample due to missing data.

** Fisher's Exact Test comparing enhanced intervention and standard intervention groups.

Preventive Health Model Factors, Prostate Cancer, and Screening

Perceptions of study participants are considered as cognitive, affective, social influence, and intention factors. The overwhelming majority (96%) of participants believed that prostate cancer could be cured if it is detected early. Eighty-six percent of the men believed that having a family history of prostate cancer increased one's risk for the disease. Ninety-five percent of the men thought that it would be easy to arrange to have a screening exam. Study participants tended to view prostate cancer screening as a salient and coherent preventive health behavior. The median score on this scale was 3.9 (where 4=strongly agree and 1=strongly disagree).

Participants had little concern about the physical and emotional discomfort associated with prostate cancer screening. Scoring for these items was reverse coded, so disagreement was reflected in a high scale score. The

median score was 3.5 (where 4=strongly agree and 1=strongly disagree). Fear of being diagnosed with prostate cancer was not a pronounced concern among men in the study, as indicated by a median score of 1.7 (where 4=strongly agree and 1=strongly disagree).

In terms of social support and influence related to screening, almost all participants said that they thought their doctor wanted them to have a prostate cancer-screening exam. Ninety-three percent of the men also said that they wanted to do what their doctor wanted them to do about screening. In relation to family influence, 87 percent of the men said that they thought family members wanted them to be screened. However, only 59 percent said that they wanted to do what family members wanted them to do about screening.

Intention to have a prostate cancer screening examination was high among study participants. The median score on this scale was 3.5 (where 4=strongly agree and 1=strongly disagree).

Delivering the Intervention

Men in both the SI Group and EI Group were mailed a copy of the prostate cancer informational booklet. In addition to receiving the booklet, men in the EI Group were contacted by a project health educator in order to arrange for a decision counseling session. The session was scheduled at the convenience of the participant, either face-to-face in the primary care practice or by telephone. A total of 60 men (60% of the EI Group) completed a decision counseling session. For 24 of these men, the session was conducted in the practice, and for 36 of them the session was conducted by telephone. Forty men did not participate in the decision counseling session for the following reasons: unavailable or could not be reached to schedule a session (n=8), refused to participate (n=9), diagnosed recently with prostate cancer or BPH or had had a recent prostate cancer-screening exam (n=20), and failed to keep their appointments (n=3). There were no statistically significant sociodemographic differences between the men who participated in the decision counseling session and those who did not.

Results of Decision Counseling Session

Decision Factors. During the counseling session, a project health educator prompted participants to identify as many reasons as possible that might affect their decision regarding prostate cancer screening. These reasons later were coded and grouped into three domains: (1) cognitive reasons to and not to screen, (2) affective reasons to and not to screen, and (3) social influence reasons to and not to screen.

Cognitive reasons to screen were cited by 80% of the men, while cognitive reasons *not* to screen were cited by 38%. The view that screening could lengthen their lives was the most widely cited positive reason. Other positive reasons included the belief that screening could increase one's quality of life and could find the cause of current health problems. Cognitive reasons not to screen included the belief that subsequent treatment might create problems like incontinence and impotence and the feeling that screening would take too much time.

Affective reasons to screen were cited by 78% of the men, while affective reasons *not* to screen were cited by only 27%. The desire to know if a health problem exists or might develop was the most widely cited positive reason, followed by the wish to resolve concerns about their health status. Affective reasons not to screen were worries that screening might be painful and embarrassing.

Social influence was cited by 63% of the men as a reason to screen, while only one person cited social influence as a reason *not* to screen. Men stated that a significant other (physician, family member, or friend) had previously encouraged them to have a screening exam. Social influence reasons not to screen included significant others urging them not to screen.

Preference Related to Screening. Men who participated in the decision counseling session were asked to make pair-wise comparisons of the three most salient decision factors on a six-point scale (i.e., overwhelmingly more influence, very much more influence, much more influence, somewhat more influence, a little bit more influence, equal influence). The men were also asked to make pair wise comparisons of decision factors on a six-point scale according to their relative importance on the decision to or not to screen (i.e., overwhelmingly more important, very much more important, much more important, somewhat more important, a little bit more

important, equal importance). The resulting values were used to compute an overall score measuring each man's preference related to screening. The patients' scores were skewed toward preferring to screen. That is, 92 percent expressed a preference to screen and only 8 percent were either unsure or preferred not to screen.

Intention to Screen. When asked to indicate their current intention regarding prostate cancer screening, 69% of the men stated that they intended to schedule a screening exam, 24% were unsure and only 7% stated that they did not intend to be screened. Intention was strongly associated with screening preference score (Fisher's Exact Test, $p=0.0002$).

Endpoint Chart Audit

Members of the research team visited the JIMA practice in order to perform an Endpoint Chart Audit for each of the study participants.

The **primary outcome**, screening utilization, was defined as the performance of both a DRE and a PSA test within six months after the informational booklet mailing. The booklet was mailed to both study groups. The Endpoint Chart Audit was conducted at least six months after the booklet mailing (median=8 months).

The **secondary outcome** expanded the definition of screening utilization. The secondary outcome was defined as

- (1) Performance of a DRE within six months before booklet mailing and a PSA test within six months after booklet mailing OR
- (2) Performance of a PSA test within six months period before booklet mailing and a DRE within six months after booklet mailing OR
- (3) Performance of a PSA test alone within six months after booklet mailing OR
- (4) Performance of both a DRE and a PSA test within six months after the booklet mailing (i.e., the primary outcome)

This definition of the secondary outcome takes into account those men who started the screening process prior to booklet mailing and completed screening after booklet mailing. It also recognizes that practitioners currently consider the PSA test alone to be a sufficient prostate cancer-screening test. As a result, they would be classified as non-screeners even if they asked to be screened during their next office visit. By expanding the observation period to include either test in the six months before the booklet mailing, we attempted to minimize this problem.

Due to the short interval between the booklet mailing and the chart audit (median=7 months), it is possible that PSA tests were performed but had not yet been entered into the patient chart by the time of the audit.

Screening Utilization

Contingency tables were computed to assess the effect of study group assignment on prostate cancer screening utilization. **Table 2** shows that in terms of the primary outcome definition, a smaller proportion of men in the EI Group were likely to have a prostate cancer screening examination than their counterparts in the SI Group (8% versus 12%, respectively). This difference was not statistically significant, however. In relation to the secondary outcome definition, screening utilization was comparable in the SI and EI Groups (18%).

Table 2. Main (Intent-to-Treat) Analyses of Primary and Secondary Screening Utilization Outcomes (N = 199)

Outcome	Screened		Odds	95% CI	p-value
	n	%	Ratio		
Screening (primary outcome)					0.357
SI (N=99)	12	12.1	1.00	Reference	
EI (N=100)	8	8.0	0.63	0.21, 1.77	
Screening (secondary outcome)					1.00
SI (N=99)	18	18.2	1.00	Reference	
EI (N=100)	18	18.0	0.99	0.45, 2.17	

SI = Standard Intervention

EI = Enhanced Intervention

P-values were computed by Fisher's Exact Test.

Since the intervention was delivered in several different forms, we also conducted an "as treated" analysis of the primary and secondary outcomes for men in the Standard Intervention group, those in the Enhanced Intervention who received no intervention, those who received their intervention by telephone, and those who were counseled in person. The results are displayed in Table 3.

Table 3. As-Treated Analysis of Screening Utilization (N = 199)

Intervention Group	N	Primary Outcome		Secondary Outcome	
		% Screened	p value	% Screened	p-value
			0.349		0.977
SI	99	12.1		18.2	
EI, no counseling	40	10.0		17.5	
EI, phone counseling	36	11.1		16.7	
EI, in-person counseling	24	0.0		20.8	

The form of the intervention did not seem to affect the likelihood that study participants would seek screening.

Endpoint Survey

All Baseline Survey responders were mailed an Endpoint Survey. This instrument was shorter than the Baseline Survey, as the research team limited the number of items in order to reduce respondent burden. In addition, a \$20 incentive was offered for survey return. A total of 137 men (69%) responded. Survey items included measures of prostate cancer screening knowledge, attitudes toward prostate cancer screening, intention to screen, decisional conflict items, items to measure impressions of the informational booklet and, for the EI Group, items to assess impressions of the decision counseling session.

Perceptions of Study Participants

Almost all respondents stated that they believed experts agreed on recommending prostate cancer screening (97%) and that prostate cancer treatment saves lives (98%). Further, almost all of the men believed that prostate cancer can be cured if discovered early (99%) and that the benefits of screening outweighed any difficulties associated with having a screening exam (95%). There was strong agreement among the men that those who undergo screening will have no more problems than those who do not (95%). Seventy-nine percent of the men said that they thought physicians could distinguish between fast and slow growing cancers. About three-quarters of the men knew that prostate cancer treatment can cause impotence and that treatment of early prostate cancer could cause incontinence (78% and 73%, respectively).

Almost all of the men felt that the screening decision was easy (93%), that the best choice was clear (96%), and that they were sure of what to do (93%). They knew what their options were (93%) and what the advantages (91%) and disadvantages (80%) were for each option. Furthermore, they felt clear about the importance of the advantages (94%) and the disadvantages (77%) of screening, and which was more important to them (92%). They felt that they had made informed choices (97%) that reflected what was important to them (98%). All of the men were satisfied with their decision and almost all expected to stick with the decision that was made (97%).

The men commonly reported that they had discussed prostate cancer screening with a doctor (85%). Of these, 96 percent indicated that the physician had recommended that they be screened. Finally, most men (90%) stated that they intended to be screened in the future.

Intervention Impact on Knowledge, Attitudes, and Beliefs

We performed univariable analyses in order to compare the SI Group and EI Group on Endpoint Survey measures of knowledge and decision conflict. Men with missing values were excluded from these analyses. As shown in Table 4, there were no significant differences between the SI Group and EI Group on these measures.

Table 4. Univariable Analyses of Attitudinal Outcomes (Scales) (n=137)

Variable	N	SI Group	EI Group	p-value
		Mean	Mean	
Knowledge Scale (0-6)	137	2.54	2.54	.833
Decision Conflict Scale (1-3)	112	1.09	1.12	.345
Certainty Subscale	112	1.06	1.14	.688
Information Subscale	111	1.15	1.18	.646
Values Subscale	111	1.16	1.17	.903
Quality Subscale	112	1.02	1.03	.353

SI = Standard Intervention

EI = Enhanced Intervention

P-values and 95% Confidence Intervals were computed from Wilcoxon's Tests.

Univariable analyses of single items measured on the Endpoint Survey are presented in Table 5. These consisted of statements which study participants were asked to agree or disagree with. The data show that men in the EI Group were more likely than men in the SI Group to believe that men who go through prostate cancer screening will have more problems than men who do not. This difference was marginally significant.

Table 5. Univariable Analyses of Attitudinal and Behavioral Outcomes (Single Items) (N=137)

	N	% agree	p-value*
"Benefits outweigh difficulties"			.718
SI Group	69	95.6	
EI Group	68	94.1	
"Early prostate cancer curable"			1.000
SI Group	69	98.6	
EI Group	68	100.0	
"Screened men have fewer problems"			.062
SI Group	69	98.6	
EI Group	68	91.2	
"Discussed screening with doctor"			.468
SI Group	67	82.1	
EI Group	67	88.1	

* p-values computed by Fisher's Exact Test

Predictors of Screening Utilization

Univariable analyses of screening utilization (both primary and secondary outcomes) were performed using demographic, cognitive, affective, and social support and influence factor variables measured on the Baseline Survey. Analyses shown in **Table 6** (primary outcome) and **Table 7** (secondary outcome) were conducted with a subset of 157 men who had complete Baseline Survey and Chart Audit data. Exact logistic regression (LogXact-4, Cytec Software Corporation) was used to calculate odds ratios and confidence intervals. Subsequently, multivariable logistic models were estimated using as predictors the effect of the intervention and those other variables that were found to predict to the primary and secondary outcomes in the univariable analyses. A generous criterion (univariable $p < 0.2$) was used for selecting predictors for initial inclusion in the multivariable models. Predictors with the largest non-significant ($p > 0.05$) p-values were then progressively excluded in a stepwise fashion until only the intervention effect and other statistically significant predictors remained.

Table 6. Univariable Analyses of Screening Utilization (primary outcome) (N=157)

	Tested (%)	Odds Ratio	(95% CI)	p-value
Study Group				0.590
SI Group	11.3	1.0	Reference	
EI Group	7.8	0.67	0.19, 2.23	
Age (years)				0.360
60 to 69	14.0	1.00	Reference	
50 to 59	7.9	0.53	0.16, 1.94	
Race/ethnicity				0.122
Non-White	14.6	1.00	Reference	
White	8.6	0.42	0.12, 1.56	
Place of birth				0.175
Philadelphia	5.6	1.00	Reference	
Other than Philadelphia	12.8	2.44	0.68, 11.0	
Education (in years)				0.562
≤ 12	12.0	1.00	Reference	
> 12	8.4	0.68	0.20, 2.45	
Marital status				0.231
Not married	14.3	1.00	Reference	
Married	7.8	0.51	0.15, 1.88	
Family history of cancer				1.000
No	9.9	1.00	Reference	
Yes	6.3	0.60	0.01, 4.57	
DRE and PSA in past year				0.594
No	8.2	1.00	Reference	
Yes	11.1	1.39	0.42, 4.57	
* Knowledge about prostate cancer		0.82	0.43, 1.68	0.611
* Salience and coherence		1.40	0.30, 9.12	0.696
* Worries and concerns		1.35	0.44, 4.65	0.618
* Perceived susceptibility		1.51	0.70, 3.24	0.277
* Curability of cancer		1.13	0.42, 4.26	1.000
* Self-efficacy		1.76	0.62, 8.56	0.418
* Social support – Physician		0.93	0.42, 2.78	1.000
* Social support -- Family Members		2.32	0.87, 10.4	0.131
* Social influence -- Physician		0.78	0.40, 1.72	0.580
* Social influence -- Family Members		0.83	0.52, 1.31	0.436
* Intention to Screen		1.13	0.63, 2.14	0.711

* Odds ratios for continuous attitudinal variables refer to a 1-point difference measured on a 4-point scale.

P-values were computed by Fisher's Exact Tests for categorical variables and exact scores tests for continuous predictors

Reference = Reference group

Table 7. Univariable Analyses of Screening Utilization (secondary outcome) (N=157)

	Tested (%)	Odds Ratio	(95% CI)	p-value
Study Group				0.679
SI Group	16.3	1.00	Reference	
EI Group	19.5	1.25	0.51, 3.09	
Age (years)				0.640
60 to 69	20.9	1.00	Reference	
50 to 59	16.7	0.76	0.29, 2.09	
Race/ethnicity				0.013
Non-White	32.4	1.00	Reference	
White	13.3	0.32	0.12, 0.85	
Place of birth				1.000
Philadelphia	18.3	1.00	Reference	
Other than Philadelphia.	17.4	0.94	0.38, 2.34	
Education (in years)				1.000
Less than or equal to 12	18.0	1.00	Reference	
More than 12	17.8	0.98	0.38, 2.69	
Marital status				0.486
Not married	21.4	1.00	Reference	
Married	16.5	0.73	0.28, 2.01	
Family history of cancer				0.308
No	19.1	1.00	Reference	
Yes	6.3	0.28	0.01, 2.00	
DRE and PSA in past year				0.407
No	15.3	1.00	Reference	
Yes	20.8	1.45	0.59, 3.62	
* Knowledge about prostate cancer		0.72	0.44, 1.22	0.193
* Salience and coherence		1.51	0.44, 6.11	0.537
* Worries and concerns		1.24	0.53, 3.11	0.626
* Perceived susceptibility		0.82	0.43, 1.52	0.551
* Curability of cancer		1.79	0.72, 5.83	0.266
* Self-efficacy		1.13	0.59, 2.49	0.761
* Social support -- Physician		0.93	0.51, 1.88	0.877
* Social support -- Family Members		1.26	0.73, 2.37	0.456
* Social influence -- Physician		1.09	0.60, 2.21	0.885
* Social influence -- Family Members		0.87	0.62, 1.23	0.444
* Intention to Screen		1.03	0.66, 1.65	0.909

* Odds ratios for continuous attitudinal variables refer to a 1-point difference measured on a 4-point scale.

P-values were computed by Fisher's Exact Tests for categorical variables and exact scores tests for continuous predictors

Reference = Reference group

Multivariable Analysis Results

Multivariable logistic regressions were conducted on the group of 157 men with complete data by including those univariable predictors from Tables 6 and 7 that had p-values less than 0.2. The initial and final models for the primary outcome are outlined in Table 8. When the demographic predictors with insignificant p-values were removed one by one from the multivariable model, only the intervention effect remained. The model then becomes identical to the univariable model, and the odds ratio and p-value for the intervention are the same as they had been in Table 6.

Table 8. Multivariable Analysis of Screening Utilization -- Primary Outcome (N = 157)

	Initial Model			Final Model		
	OR *	95% CI	p value	OR *	95% CI	p value
Intervention Group			0.596			0.590
Standard	1.00	Reference **		1.00	Reference**	
Enhanced	0.73	0.20, 2.49		0.67	0.19, 2.23	
Race			0.119			-- --
Non-White	1.00	Reference**				
White	0.42	0.12, 1.55				-- --
Birthplace			0.172			
Philadelphia	1.00	Reference**				
Other	2.52	0.70, 11.46				
* Odds ratio						
** Reference group						

Men in the Enhanced Intervention Group were less likely to be screened than those in the Standard Intervention Group. Similarly, non-Whites were less likely to be screened than Whites were. However, men born outside of Philadelphia were more likely to be screened than men born in Philadelphia were. None of these effects were statistically significant.

A similar multivariable model was constructed for the secondary outcome. The initial and final models are reported in Table 9.

Table 9. Multivariable Analysis of Screening Utilization -- Secondary Outcome (N = 157)

	Initial Model			Final Model		
	OR *	95% CI	p value	OR *	95% CI	p value
Intervention Group			0.403			0.522
Standard	1.00	Reference		1.00	Reference	
Enhanced	1.44	0.57, 3.92		1.41	0.56, 3.62	
Race			0.023			0.012
Non-White	1.00	Reference		1.00	Reference	
White	0.33	0.13, 0.90		0.31	0.12, 0.74	
* Odds ratio						
** Reference group						

Compared with the Standard Intervention Group, the Enhanced Intervention group was more likely to be screened as defined by the secondary outcome. Note: The direction of this effect is in contrast with that for the primary outcome. Importantly, the data show that Whites were significantly less likely to be screened than non-Whites were.

Key Research Accomplishments

- Design and field-testing of an Educational Booklet
- Development of the Counseling Session Protocol
- Administration of a Baseline Survey to 199 men
- Implementation of the Counseling Session for 60 men in the Enhanced Intervention Group
- Completion of an Endpoint Chart Audit for all 199 study participants
- Administration of an Endpoint Survey to 137 participants
- Analysis of hypothesis H1 and H2a-e
- Analyses of predictors of prostate cancer screening

Reportable Outcomes

Publications

- Myers RE. African American men, prostate cancer early detection examination use, and informed decision-making... *Seminars in Oncology* 26:375-381, 1999.
- Myers RE and Kunkel EJS. Preparatory education for informed decision-making in prostate cancer early detection and treatment. *Seminars in Urologic Oncology* 18(3):172-177, 2000.
- Kunkel EJS, Bakker JR, Myers RE, Oyesanmi OA, and Gomella LG. Biopsychosocial aspects of prostate cancer. *Psychosomatics* 41:85-94, 2000.

Kunkel EJS, Myers RE, Lartey PL, and Oyesaami OA. Communicating effectively with the patient and family about treatment options for prostate cancer. *Seminars in Urology* 18:233-240, 2000.

Liberatore MJ, Myers RE, Nydick RL, Steinberg M, Brown ER, Gay R, Powell T, Powell RL. Decision Counseling for Men Considering Prostate Cancer Screening. *Computers and Operations Research* 30:1421-1434, 2003.

Kunkel EJS, Meyer B, Daskalakis C, Cocroft J, Jennings-Dozier K, Myers RE. Behaviors Used by Men to Protect Themselves Against Prostate Cancer. *Cancer Epidemiology, Biomarkers and Prevention* (in press)

Presentations

Liberatore MJ, Nydick RL, Myers RE, Kunkel EJS, O'Connor J, Christian E, Burgh D, Wolf T, Ohene-Frempong J. A decision support system for men considering prostate cancer early detection. Institute for Operations Research and the Management Sciences, Philadelphia, PA, 1999.

Myers RE. Intention to be Tested for Prostate Cancer Risk among African American Men. Society for Behavioral Medicine, 22nd Annual Scientific Sessions, Seattle, WA, March 21-24, 2001.

Decision Counseling and Health Behavior Decision Making. National Cancer Institute and the Federation Forum on Research Management. Decision-Making: Making Good Decisions under Conditions of Uncertainty. Washington, DC, November 21, 2003.

Materials and Methods

During the course of the study, the research team continued to refine the intervention methods and materials used in this study. These activities have led to the development of a decision counseling protocol that is applicable for use in facilitating informed, value-based decision making about prostate cancer screening. The methods and materials now available for use are listed below:

- An brochure that includes information about prostate cancer and alternative decisions about screening utilization. It also includes pros and cons associated with each alternative and allows the individual to write in factors (decision factors) that are likely to encourage and discourage each alternative.
- A ratio abacus that allows the patient/client to indicate the magnitude of influence each decision factor is likely to have on choice and the level of importance each decision factor has relative to other decision factors.
- A computer software program and that enables the trained professional to enter patient/client responses, compute a decision preference score, and display results. The software also allows for creation of a database of responses and scores.

Conclusions

We have created a unique informed decision-making intervention, recruited potential study participants, implemented the intervention, collected baseline and endpoint survey data, conducted chart audits for the participants, and analyzed this information.

We designed a 13-page booklet summarizing epidemiological and clinical information related to prostate cancer screening. It was reviewed by faculty from the Departments of Radiation Oncology and Urology at Thomas Jefferson University and further developed in face-to-face interviews with 20 patients from Jefferson Internal Medicine Associates. The Pennsylvania Division, Inc. of the American Cancer Society has adopted the booklet for use in public education. In addition, the Centers for Disease Prevention and Control have requested copies for use in educational outreach.

We successfully recruited and administered a baseline survey to a sample of 199 men. The survey respondents were then randomized into two groups: a Standard Intervention Group, which received an informational booklet, and an Enhanced Intervention Group, which was targeted with the informational booklet and a decision counseling session with a health educator. We were able to deliver the decision counseling session to 60% of the EI Group. For most of these men, the decision counseling session was delivered by telephone. An Endpoint Survey measured post-intervention knowledge, attitudes, and beliefs toward prostate cancer and screening. An Endpoint Chart Audit was conducted to assess the impact of the intervention on behavior.

We conducted univariable and multivariable analyses of the effects of numerous baseline survey predictors on both the primary and secondary outcomes. In terms of the primary outcome, there was suggestive evidence that Whites and non-Whites responded quite differently to the intervention. The difference was not statistically significant, however. Relative to the secondary outcome, African American men increased their screening utilization in response to receiving information about prostate cancer screening, while White men decreased their utilization. Similar findings have been reported elsewhere. The reason(s) for this phenomenon are unclear. It may be that African American men saw themselves at greater risk for prostate cancer and ultimately were more influenced by this factor. It is also possible that African American men were more reticent than white men to lend credence to the message that prostate cancer screening may not be entirely beneficial. Further, it is possible that physicians provided stronger encouragement of screening to African American men than to white men. Further research is needed to explore more fully the issue of differential intervention impact among racial/ethnic groups.

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U.S. Army Medical Research and Material Command
Value Based Decision-Making in Prostate Cancer Early Detection
Final Report

Appendices

Journal Articles

- Myers RE. African American men, prostate cancer early detection examination use, and informed decision-making... *Seminars in Oncology* 26:375-381, 1999.
- Myers RE and Kunkel EJS. Preparatory education for informed decision-making in prostate cancer early detection and treatment. *Seminars in Urologic Oncology* 18(3):172-177, 2000.
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- Kunkel EJS, Myers RE, Lartey PL, and Oyesaami OA. Communicating effectively with the patient and family about treatment options for prostate cancer. *Seminars in Urology* 18:233-240, 2000.
- Liberatore MJ, Myers RE, Nydick RL, Steinberg M, Brown ER, Gay R, Powell T, Powell RL. Decision Counseling for Men Considering Prostate Cancer Screening. *Computers and Operations Research* 30:1421-1434, 2003.
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Study Materials

- Is Being Checked for Prostate Cancer a Good Idea or Bad Idea?* NOTE: This is a photocopy of a two-color information booklet
- Reasons for Being Tested and for Not Being Tested for Early Prostate Cancer. NOTE: This is used during the decision counseling intervention.
- Preference and Decision Related to Prostate Cancer Early Detection. NOTE: This summary sheet prepared with the patient by the counselor during the decision counseling intervention.

Study Data Collection Instruments

- Survey on What You Think about Prostate Cancer Screening (mailed version of baseline survey)
- Follow-up Survey on What You Think about Prostate Cancer Screening (mailed version of endpoint survey)
- Chart Audit Form (conducted after study endpoint)

African American Men, Prostate Cancer Early Detection Examination Use, and Informed Decision-Making

Ronald E. Myers

It is well known that African American men are more likely to be diagnosed with metastatic prostate cancer than White men. Racial variation in the use of prostate cancer early detection modalities (ie, digital rectal examination [DRE] and prostate-specific antigen [PSA] testing) has been suggested as a major reason for this differential. Several factors may help to explain the reported low levels of DRE and PSA test utilization among African American men, including background sociodemographic characteristics, medical history, and cognitive and psychosocial perceptions. In this review, the impact of these characteristics on prostate cancer early detection examination utilization is explored. Findings from studies showing race-related differences in cognitive and psychosocial factors are presented. Preparatory education for informed decision-making is suggested as an approach to help minimize racial differences in cognitive and psychosocial factors that influence the use of prostate cancer early detection modalities. The need to facilitate informed decision-making along the continuum of care is highlighted. *Semin Oncol* 26:375-381. Copyright © 1999 by W.B. Saunders Company.

PROSTATE CANCER is the most frequently diagnosed cancer and is the second leading cause of cancer death among men. It is estimated that in 1999, there will be 179,300 new cases of prostate cancer and an estimated 37,000 deaths from the disease in the United States.¹ One in six men will be diagnosed with prostate cancer during their lifetime. Most men who are newly diagnosed with prostate cancer will have the disease detected by a prostate cancer early detection examination. The prostate cancer early detection examination usually includes both a digital rectal examination (DRE) and prostate-specific antigen (PSA) test. Abnormal results are often followed by a transrectal ultrasound and biopsy.

Incidence rates (per 100,000) for prostate cancer are substantially higher for African American men than other racial and ethnic groups in the United States (African American, 224.3; White, 150.3; Hispanic, 104.4; Asian/Pacific Islander, 82.2; American Indian, 46.4). The mortality rate for this disease is also dramatically higher among African American men versus other groups (African American, 55.0%; White, 24.1%; Hispanic, 16.8%; Asian/Pacific Islander, 10.9%; American Indian, 14.2%). Further, across all stages of prostate cancer, African

American men have relatively low 5-year survival rates compared with White men (81% v 95%, respectively).¹

Racial variation in the utilization of prostate cancer early detection modalities (ie, DRE and PSA testing) has been observed. More specifically, African American men appear less likely to have a DRE and PSA test in the absence of symptoms than White men.²⁻⁷ As a result, African American men are more likely to be diagnosed with metastatic disease.^{8,9}

FACTORS THAT MAY INFLUENCE PROSTATE CANCER EARLY DETECTION EXAMINATION USE

Health behavior theory suggests a number of factors that may influence the utilization of cancer early detection modalities such as the DRE and PSA test.¹⁰⁻¹² These factors include personal background (eg, sociodemographic characteristics and medical history), cognitive and psychological representations, social support and influence, intention to engage in preventive behavior, and exposure to educational programs, and help to predict actual preventive behavior. On a personal level, background may be defined in terms of age, gender, race, income, education, marital status, and medical history. Each of these characteristics subsumes an underlying experiential frame of reference that conditions individual perceptions of health-related stimuli encountered in everyday life. Cognitive and psychological representations are the perceptions of specific health threats, procedures that are available for coping with the threat, and outcomes that are likely to result from coping efforts. One's view of the threat is shaped by cognitive notions related to susceptibility or risk, severity, cause, and curability of disease, along with the emotional

From the Behavioral Epidemiology Section, Division of Medical Oncology/Medical Genetics, Department of Medicine, Thomas Jefferson University, Philadelphia, PA.

Address reprint requests to Ronald E. Myers, PhD, Behavioral Epidemiology Section, Division of Medical Oncology/Medical Genetics, Department of Medicine, Thomas Jefferson University, 125 S Ninth St, Suite 403, Philadelphia, PA.

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reactions that such notions elicit. Individuals also consider the procedure(s) that may be used to cope with an acknowledged health threat in terms of technical effectiveness, practical convenience, personal benefit, and importance to well-being. Social support and influence are factors that refer to the individual's perceptions about the stance that significant others have taken or are likely to take in relation to the threat or the procedure(s) that are available to cope with the threat. Self-reported intention signals the extent to which the individual is oriented toward engaging in a given coping behavior. Further, exposure to behavioral prompts or interventions by health care providers can serve as a strong, direct prompt to behavior. Relatively little research has been performed to identify possible predictors of prostate cancer early detection use among African American men.

PERCEPTIONS RELATED TO EARLY DETECTION EXAMINATION AMONG AFRICAN AMERICAN MEN

In a community-based investigation in Florida, Smith et al¹³ conducted face-to-face interviews about prostate cancer early detection with 556 African American men aged 40 years or older. Sixty-nine percent of the men were 50 and older, 18% had more than a high school education, and 48% were married. It was found that 91% of the men believed that prostate cancer can be cured. Two thirds of the respondents thought a man can have prostate cancer without having any symptoms. However, only 58% felt it was necessary to have an early detection examination in the absence of symptoms. In terms of susceptibility, just 42% of the participants believed that family history confers increased risk, and fewer than one third thought that African American men have a higher risk of prostate cancer than White men.

Myers et al¹⁴ conducted a study to identify factors associated with intention to have a prostate cancer early detection examination among African American men. Telephone survey data were obtained from 218 African American men who were 40 to 70 years of age. Men in the study were randomly selected from the patient population of a large primary care practice in Philadelphia. Forty-three percent of the men were 50 years of age or older, 41% had more than a high school education, and 65% were married. Almost two thirds of the respondents perceived the risk of prostate cancer

among African American men to be high. However, only 30% rated their personal risk for prostate cancer as high. Fifty-nine percent of the men viewed having an early detection examination to be a salient and coherent preventive health behavior, and 58% considered it to be efficacious. A substantial proportion of survey participants (41%) expressed concern about DRE-related discomfort and embarrassment, 63% were worried about having an abnormal early detection examination result, and 18% believed that having an early detection examination might cause them to have sexual problems. Forty-three percent of the men were also concerned about the financial expense of an early detection examination. In terms of social support, 55% of the respondents believed that their physicians and significant others would encourage them to have a prostate cancer early detection examination. Study participants were asked to indicate whether they intended to have a prostate cancer early detection examination in the future. Sixty-nine percent reported that they intended to do so. Multivariate analyses showed that perceived examination efficacy and physician support for early detection were significantly associated with the intention to have an early detection examination.

PREDICTING EARLY DETECTION EXAMINATION USE AMONG AFRICAN AMERICAN MEN

Recently, Myers et al¹⁵ concluded a randomized trial of an educational intervention designed to encourage African American men to present at a urology clinic for prostate cancer education and early detection. Baseline telephone survey data were collected for 413 study participants in Chicago who were 40 to 70 years of age. The men were then randomly assigned to either a minimal or enhanced intervention group. Men in the former group were mailed an introductory letter that invited them to the clinic and a reminder letter. Men in the enhanced intervention group received the same correspondence and were provided a personalized educational booklet plus a telephone call that was designed to highlight educational messages included in the booklet. At the clinic, men were required to complete an informed-consent form prior to having an early detection examination.

At baseline, 59% of the study participants

believed that African American men are at increased risk for prostate cancer compared with White men. However, only 14% of the respondents thought they themselves had a high risk for developing prostate cancer and 19% were worried about being diagnosed with the disease. Most (86%) believed that prostate cancer can be cured and that men should have an early detection examination before symptoms occur (79%). Men in the study tended to believe that prostate cancer early detection is salient and coherent preventive health behavior (89%), the early detection examination is efficacious (92%), and early detection has a positive impact on well-being (95%). Many of the men also expressed concern about examination-related physical discomfort and embarrassment (45% and 48%, respectively); and one fifth of the men believed that having an early detection examination can cause health problems. Most respondents believed that their primary care physician and family members supported prostate cancer early detection (70% and 76%, respectively).

Results of multivariate analyses showed that men who were assigned to the enhanced intervention group were significantly more likely to schedule and keep a clinic appointment than men in the minimal intervention group (51% and 29%, respectively). All but one of the men who presented for an appointment chose to have an early detection examination. Other significant predictors were older age (>50 years), married status, the belief that one should have a prostate cancer early detection examination before symptoms occur, and self-reported intention to have an examination.

Elsewhere, Tingen et al⁶ studied the response of African American men to an educational program that was offered through various community sites (eg, worksites, churches, housing projects, and barbershops) in central South Carolina. The program included information on prostate cancer, a description of the American Cancer Society guidelines for DRE and PSA test utilization to detect early prostate cancer, and educational messages that strongly promoted routine use. Some men (n = 343) received the program as a standard intervention. For others (n = 259), the standard intervention was supplemented by a testimonial about prostate cancer early detection provided by a peer. Still other men (n = 294) received the standard program plus a reminder telephone call from a social worker. Finally, some men (n = 315)

were provided the standard intervention plus both the testimonial and reminder telephone call. All program attendees were provided a voucher to take to a primary care physician for a free DRE and PSA test. Mailed reminders were also used to encourage adherence to prostate cancer early detection. Baseline survey measures (ie, age, education, income, prior DRE and PSA test use, and exposure to intervention) were examined in multivariate analyses of adherence to prostate cancer early detection. Results of these analyses showed that men who were older and who received either the testimonial or the telephone call reminder were significantly more likely to have a prostate cancer early detection examination. Intervention effects were as follows: standard intervention, 52%; standard intervention and testimonial, 59%; standard intervention and telephone call, 66%; and standard intervention plus testimonial and telephone call, 68%.

Elsewhere, Powell et al¹⁶ showed that a community-based educational program involving African American churches was successful in encouraging prostate cancer early detection among men who were 40 to 70 years of age. The program involved a presentation by African American physicians and prostate cancer survivors at the church. Following the presentation, medical staff were on hand to collect serum samples for use in PSA testing. During the course of 1 year, more than 1,000 men who attended one of the church-based presentations decided to have a PSA test.

The summarized findings show that measures of background, cognitive and psychological representations, social support and influence, and exposure to educational interventions can be used to identify African American men who are likely to choose to have and not to have a prostate cancer early detection examination. In this regard, being older, believing that one should not wait for symptoms before undergoing an early detection examination, having faith in the efficacy of the examination process, and having trusted lay and professional support for early detection are factors that seem to predispose men to take preventive action. Only a limited amount of research on racial variation in such predictors has been reported.

RACE AND FACTORS RELATED TO PROSTATE CANCER EARLY DETECTION

Demark-Wahnefried et al¹⁷ reported the results of a survey administered to 1,504 men who pre-

sented for DRE and PSA testing at nine southeastern sites that participated in the 1992 National Prostate Cancer Awareness Week. Survey findings showed that African American men tended to have less formal education and were less likely to be married than White men. African American men were more likely to report health problems but less likely to have a primary care physician. Fewer African American men indicated that they had ever had a DRE or PSA test. In relation to perceptions about prostate cancer and early detection, African American men were less likely than White men to report that they knew someone who was diagnosed with prostate cancer to believe that "a man with prostate cancer can have a normal life," and to know that "men can have prostate cancer without symptoms." African American men were more likely to believe that prostate cancer treatment causes impotence.

McCoy et al¹⁸ administered a telephone survey to 897 men in Florida. The men identified themselves in terms of race/ethnicity as follows: 271 (31%) African American, 284 (33%) White, and 314 (36%) Hispanic. African American men in the sample tended to have less formal education than either White or Hispanic respondents. Both African American and Hispanic respondents had lower levels of income than White respondents. In addition, fewer African American and Hispanic men reported ever having a DRE as compared with White men. African American and Hispanic men were also more concerned about examination-related discomfort and embarrassment than White men. The authors reported that African American men tended to be more pessimistic about the prospects of curing prostate cancer as compared with White and Hispanic men.

Weinrich et al⁷ collected and analyzed baseline survey data for 319 (33%) men who attended a community-based educational presentation about prostate cancer early detection and reported never having a DRE or PSA test. Of this number, 260 (82%) were African American. The African American attendees, as compared with White attendees, had less formal education, a lower level of income, and less knowledge about whether they had a family history of prostate cancer, and were more likely to report having pain in the lower back, hips, thighs, testicles, or rectum during the prior year. Similar results were reported for analyses that were performed within community sites.^{19,20}

Findings of the studies reported here suggest that African American men, as compared with White men, tend to have less knowledge about prostate cancer, less favorable views about early detection and the consequences associated with treatment, and less social support for taking preventive action. Educational interventions of the type described earlier may serve to effectively minimize racial differences in cognitive and psychosocial factors associated with DRE and PSA test use. As a consequence, their use may increase the proportion of African American male prostate cancer patients who have an early detection examination and are diagnosed with early disease. However, it is important to point out that current controversies about prostate cancer early detection and treatment require close consideration of educational intervention goals.

CONTROVERSIES ABOUT PROSTATE CANCER EARLY DETECTION

Proponents of prostate cancer screening observe that combined DRE and PSA testing is effective for identifying men with early prostate cancer, and that men who are diagnosed with and treated aggressively for localized prostate cancer have higher survival rates compared with men diagnosed with late-stage disease.^{21,22} Further, it has been argued that the use of DRE and PSA testing is justified for asymptomatic older men who have a reasonable life expectancy and are at increased risk (ie, African American men and men with a family history of prostate cancer).^{23,24} The American Urological Association²⁵ and American Cancer Society²⁶ suggest that men aged 50 years or older with a life expectancy of at least 10 years should be offered DRE and PSA testing on an annual basis.

However, caution has been urged regarding the routine use of DRE and PSA testing for prostate cancer early detection, because no randomized trials have demonstrated that early detection can reduce mortality from prostate cancer.^{27,28} Unfortunately, results of randomized trials designed to answer this question will not be available for a number of years.²⁹⁻³¹ Concern about prostate cancer early detection is also based on the fact that the treatment of early-stage prostate cancer can cause substantial adverse outcomes (eg, impotence, incontinence, stricture, bowel injury, and death).^{32,33} Guidelines proposed by the US Preventive Services Taskforce and the Canadian Taskforce on the

Periodic Health Examination recommend that DRE and PSA testing should not be performed to screen for early prostate cancer.^{34,35} The American College of Physicians has recommended against routine prostate cancer screening among older adult men, and has suggested that men be advised about the potential benefits and harms of prostate cancer early detection prior to examination performance.³⁶

The differences of opinion summarized here highlight the need for informed decision-making regarding prostate cancer early detection. It is especially important to develop approaches that can be used to prepare African American men to decide whether to have an early detection examination, given the extraordinary burden of prostate cancer in this population group.

PREPARATORY EDUCATION FOR INFORMED DECISION-MAKING

Myers et al¹⁵ showed that a personally tailored package of print materials and telephone contacts can have a strong effect on the adherence behavior of African American men. In their study, a "two-step" educational intervention process was used. That is, men were initially encouraged to make an office visit to obtain information about prostate cancer and to decide whether to have an examination. Then, at the visit, informed consent was obtained before an early detection examination was performed. Once the men responded to the intervention by making an office visit, exposure to the informed-consent process made no difference in whether they had an early detection examination.

Flood et al³⁷ reported similar results in a study that involved men who presented at a medical clinic to have a prostate cancer early detection examination. In that investigation, men were randomly assigned to view either a videotape that described prostate cancer, early detection, and treatment consequences or a videotape that encouraged having an examination. No difference in adherence to the examination was observed in the two groups. It is important to note that the results of their study pertain to men who came to a clinic ready to consider having an early detection examination. It may be that among these men, the in-office presentation was viewed as reinforcing the decision to have an examination. Alternatively, men who visited the office may not have

fully attended to or understood the informational content at hand.

Findings from other studies in the area of decision-making about prostate cancer early detection support the view that more cautionary educational interventions are likely to decrease the interest in having a PSA test among men who have not yet considered having an early detection examination. Wolf et al³⁸ reported the results of a study involving men who presented at a primary care physician office for an outpatient appointment. Men who were exposed to a detailed description of the pros and cons of prostate cancer early detection were less likely to be interested in having an examination than those who were exposed to a brief statement that the examination was available. In another study reported in the same article, older adult men who scheduled a visit at a general internal medicine clinic were randomly assigned to view a videotaped presentation that described prostate cancer early detection in cautionary terms versus no videotape. Men in the former group were much less likely to have a prostate cancer early detection examination than men in the latter group. It is likely that the equivocal nature of the more intensive educational messages discouraged having an examination.

Population background and cognitive and psychosocial factors should be considered in organizing educational programs intended to influence attitudes and behavior related to prostate cancer early detection among African American men. New approaches for facilitating informed decision-making about having an early detection examination are needed. The educational content of such preparatory education methods should focus on clarifying the purpose and pros and cons of having an early detection examination. Preparatory education of this sort should aim to elicit individual values and relate personal preferences to the prospect of taking preventive action. Attention should be given to involving the significant others of at-risk men in the decision-making process.

Coley et al³⁶ have observed that the optimal way to enable people to systematically consider the available information about prostate cancer care, to weigh the pros and cons of having an early detection examination, and to make informed judgments about medical care is not known. Although "shared decision-making" has been promoted as a method for involving patients and

practitioners in this process,³⁹ Deber⁴⁰ has asserted that preparatory education may be needed prior to the physician-patient encounter. Preparatory education should enable individuals to engage the practitioner in the process of deciding about the personal use of available prevention and treatment alternatives. When provided early in the process of care, preparatory education can serve to facilitate interactions between informed parties, including the supportive others of the patients. Such interactions are likely to be especially helpful in areas where there is a high degree of uncertainty regarding potential consequences.

Ubel⁴¹ has observed that although a variety of methods (eg, printed and verbal descriptions of behavioral alternatives, decision boards, videos, and interactive videodiscs) have been used to make information about prostate cancer early detection available, little is known about their impact on the knowledge, attitudes, and beliefs of asymptomatic men who are in the position of having to decide whether or not to have an early detection examination.⁴² Onel et al⁴³ reported on the successful use of video education in conjunction with physician encounters in preparing diagnosed prostate cancer patients for decision-making.

Chan and Sulmasy⁴⁴ have recently outlined the content that they believe to be appropriate for inclusion in an educational intervention aimed at facilitating informed decision-making about prostate cancer early detection. Prior to PSA testing, they recommend that, at a minimum, men should be advised that false-positive and false-negative results may occur and that it is not known whether PSA testing reduces prostate cancer mortality. They suggest that additional information about the pros and cons of prostate cancer early detection may be provided in the context of an encounter with a health care professional and via print materials.

FUTURE DIRECTIONS FOR RESEARCH

In the future, special attention should be devoted to examining the impact of preparatory education on informed decision-making about early detection in different high-risk population groups, including African American men and men with a family history of prostate cancer. The effects of preparatory education, as measured in terms of knowledge change, satisfaction with decision-

making, and behavior, should be assessed across the continuum of care. That is, in addition to preparing men to decide whether to undergo DRE and PSA testing, it is also important to facilitate decision-making about diagnostic evaluation and treatment. Recent reports suggesting that nonadherence to recommended follow-up treatment may be substantial among men with an abnormal early detection examination result⁴⁵ and that there may be significant racial differences in the use of aggressive therapy amplify the need for additional research in the area of preparatory education.⁴⁶⁻⁴⁸

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Preparatory Education for Informed Decision-Making in Prostate Cancer Early Detection and Treatment

Ronald E. Myers, PhD, and Elisabeth J. S. Kunkel, MD

Patients are expected to assume increased responsibility for self-management in health care. However, little attention has been directed to the problem of preparing individuals to play a more active role in the physician-patient relationship. Preparatory education about prostate cancer early detection and treatment is needed to enable patients to recognize the importance of their role in medical decision-making, voice personal values and preferences related to health care choices, and make informed choices under conditions of uncertainty about possible outcomes. Effective decision aids are needed to facilitate shared decision-making in the context of the physician-patient relationship along the continuum of prostate cancer care. Decision aids for patients have taken the form of informational booklets, scripted telephone counseling, decision boards, educational videotapes, interactive videodiscs, computer programs, and Internet Web sites. The impact of preparatory education and the use of decision aids should be evaluated in terms of change in knowledge and understanding, shifts in decision preferences, health care utilization, and satisfaction with care. The need for this type of patient interaction will grow as technology increases patient access to health care information.

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Key words: Prostate cancer, screening, treatment, decision aids, and shared decision-making.

The American Urological Association¹ and the American Cancer Society² recommend that men who are 50 or more years of age and have a life expectancy of 10 or more years should be offered a digital rectal examination (DRE) and a prostate-specific antigen (PSA) test on an annual basis and that screening should be considered at an earlier age for men under 50 years who are at high risk (ie, African

American men and men with a family history of prostate cancer). Guidelines put forward by the United States Preventive Services Taskforce and the Canadian Taskforce on the Periodic Health Examination do not support routine prostate cancer screening.^{3,4} The American College of Physicians has also recommended against prostate cancer screening among older adult men and has suggested that if screening is performed, men should be advised in advance about the potential benefits and harms of prostate cancer early detection.⁵ This lack of consistency in recommendations reflects the fact that there are different interpretations of the available scientific evidence on prostate cancer early detection.

Health care professionals who support routine prostate cancer screening point out that combined DRE and PSA testing is effective at identifying men with early prostate cancer. In addition, they cite evidence that men who are diagnosed with localized prostate cancer and are treated aggressively have higher survival rates compared with men who are diagnosed with late-stage disease.^{6,7} Opponents of prostate cancer screening argue that no randomized trials have demonstrated a reduction in mortality as a result of prostate cancer screening.^{8,9} In addition, they assert that it is not yet possible to reliably differentiate indolent from aggressive prostate cancer, and that treatment of early-stage prostate cancer with radical prostatectomy or radiation therapy can cause substantial adverse outcomes (eg, impotence, incontinence, stricture, bowel injury, and even death).^{10,11} The arguments outlined herein give many men pause as they consider whether or not to have a screening DRE and PSA test. Unfortunately, results of current randomized trials that are designed to determine whether detecting and treating early prostate cancer has an impact on mortality will not be available for several years.¹²⁻¹⁴

Men who have been diagnosed with tumors confined to the prostatic capsule are concerned about reports that show incontinence and sexual performance to be significant problems for men treated with either radiotherapy or radical prostatectomy.¹⁵

From the Departments of Medicine and Psychiatry and Human Behavior, Jefferson Medical College, Philadelphia, PA.

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Address reprint requests to Ronald E. Myers, PhD, Behavioral Epidemiology, Division of Medical Oncology/Medical Genetics, Department of Medicine, Thomas Jefferson University, 125 South 9th St, Suite 403, Philadelphia, PA 19107.

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A case in point is the results of a recent population-based longitudinal cohort study of patients with localized prostate cancer. The study showed that at 10 months after radical prostatectomy, 8% of the men were incontinent and 60% were impotent.¹⁶ Although prostate cancer treatment techniques have improved substantially and new options will emerge in the future, the elimination of negative side effects from therapy will remain an elusive goal.

It has been well documented that older adult men are not well informed about the nature of prostate cancer, the early detection and treatment alternatives available, and controversies related to prostate cancer early detection outlined above.¹⁷ In addition, it is likely most men are simply not fully cognizant of the fact that choosing to have an early detection examination may require further decisions about undergoing diagnostic evaluation and treatment. There is an acute need for effective preparatory educational materials and methods that can be used to help patients make meaningful health care choices about prostate cancer early detection. Preparatory education materials and methods are also needed to facilitate informed decision-making further along the continuum of care.

Preparatory Education for Informed Decision-Making

In a review of the patient education literature, van den Borne¹⁸ noted that today patients are being asked to assume an increasing level of responsibility for self-management of personal health care. This trend has stimulated work that is directed towards developing ways of empowering patients to become equal partners along with health care professionals in the process of maintaining health and well-being.

The notion that patients and their physicians should routinely engage in "shared decision-making"¹⁹ about health-related issues is indicative of a paradigm shift in the physician-patient relationship. The shared decision-making paradigm, which defines the physician and patient as co-participants in a process of managing personal health and well-being, has largely supplanted the more traditional model in which the medical practitioner assumes most of the responsibility for choosing a health care strategy that is in the best interests of the patient.

There are a number of obstacles to achieving the ideals of shared decision-making. First, patients vary in terms of their familiarity with medical terminology, beliefs about health and illness, and readiness to consider multiple alternatives. Second, research has sug-

gested that patients generally want to receive as much information as possible about options available to them.^{20,21} However, in contrast to the desire for information, there appears to be great variation in the extent to which patients wish to be involved in treatment decisions.^{22,23} Many patients still view physicians as experts who can give them the "right decision" that should be made to resolve uncertainties in health care. Such patients may perceive active personal involvement in the process of choosing among options to be inappropriate or irrelevant and may refuse to play an active role in decision-making. Second, it is important to consider how information should be presented; patients vary in terms of their familiarity with medical terminology, beliefs about health and illness, and readiness to consider multiple alternatives.

Physicians, themselves, differ in how effectively they convey complex medical information in a manner that is easily understood and level of commitment to facilitating shared decision-making. Furthermore, if a goal is to maintain patient autonomy, then it is crucial that information be presented in a way that does not serve to systematically influence patient decision-making about whether or not to opt for screening. However, there is question as to how, and whether, "nondirectiveness" can be achieved. For example, it has been suggested that simply offering someone a test implies the recommendation to accept that offer.²⁴ Alternatively, a recent study suggests that the extent to which individuals are encouraged to consider or explore different issues related to testing significantly influences decision-making.²⁵

Other factors that serve to shape the practice environment, such as the amount of time that is available for physicians to devote to discussions of complex health care issues with patients, may further constrain the extent to which the goal of shared decision-making can be achieved.²⁶

Decision Aids in Prostate Cancer Early Detection and Treatment

To facilitate informed decision making, it is important to enable patients to recognize the importance and legitimacy of their role in medical decision-making, consider personal values and preferences related to the choices at hand, and clarify the implications of choosing from among different health care alternatives. Research is increasing on the development of decision aids that may be used to accomplish

these goals in relation to prostate cancer early detection and treatment.

In an urban community study conducted in Michigan, media announcements were used to recruit men to undergo prostate cancer screening with DRE and PSA testing.²⁷ Men completed a baseline survey questionnaire at the screening site, viewed an educational videotape, and filled out an exit survey. At baseline, African American men were significantly less knowledgeable about prostate cancer and screening at baseline than white men. Analyses of exit survey data found that there was no longer a race-related knowledge difference. These findings suggest that an educational videotape can help to minimize knowledge differences about prostate cancer and screening.

Volk et al²⁸ reported on a study concerning the prostate cancer knowledge of 160 men who were 45 to 70 years of age and who presented at a university-based family medicine clinic for scheduled office visits. Men who completed a baseline survey were randomly assigned either to a control group or an intervention group. Men in the intervention group were shown a 20-minute videotape that presented information on the pros and cons of PSA testing. Two weeks after the office visit, an endpoint survey was administered. It was determined that men in the intervention group provided more accurate responses to survey items that concerned early prostate cancer mortality rates, performance characteristics of PSA testing, and treatment-related complications compared with control group men. The authors concluded that exposure to the videotape decision aid enhanced the capacity of study participants to make an informed decision about having a prostate cancer early detection examination.

Wolf et al²⁹ published results of a study involving older adult men who presented at a primary care physician office for an outpatient appointment. Men who were exposed to a detailed description of the pros and cons of prostate cancer early detection were less likely to be interested in having an examination than those who were exposed to a brief statement that the examination was available. In another study reported in the same article, older adult men who visited a general internal medicine clinic were randomly assigned either to an intervention group that viewed a videotape, which described prostate cancer early detection in cautionary terms, or to a control group. Men in the intervention group were much less likely to have a prostate cancer early detection examination than men in the control group. It is likely that the equivocal nature of the more intensive educational

messages discouraged men from having an examination.

Myers et al³⁰ randomly assigned 413 African American men who were 40 to 70 years of age either to a minimal or enhanced intervention group. The former group received an introductory letter that invited them to visit a urology clinic to receive information about prostate cancer early detection and to decide whether to have an early detection examination (DRE and PSA testing). The latter group received the same contact plus a personally tailored educational booklet and follow-up telephone counseling related to prostate cancer early detection. At the clinic, men from both groups were provided print materials that described the pros and cons associated with prostate cancer early detection. If the participant chose to have an examination, he was asked to sign a written consent for testing. Findings from the study showed that men in the enhanced intervention group were significantly more likely than men in the minimal intervention group to make a clinic visit and have an early detection examination (51% and 29%, respectively).

In relation to preparatory education about prostate cancer treatment, Schapira et al³¹ conducted a pretest and post-test evaluation of a videotape decision aid that was designed to assist patients considering treatment options for clinically localized prostate cancer. The study involved 32 men who were 50 to 85 years of age and did not have prostate cancer. Analyses of survey data indicated that exposure to the videotape increased participant knowledge about treatment options and possible outcomes and generated increased interest in playing an active role in treatment decision-making.

Davison and Degner³² conducted a study that was designed to assess the impact of an informational decision aid on prostate cancer patient anxiety and depression and on patient role in decision making. Sixty newly diagnosed patients from a community urology clinic in Canada were randomly assigned to receive either a package of print information that included a list of questions to ask the treating physician during medical consultation (N = 30) or the information package plus an audiotape of the consultation (N = 30). Baseline and postconsultation survey measures were obtained for patient-preferred decisional role and for anxiety and depression. Findings from the analysis of survey data showed that men in both study groups chose to play an increasingly active role in treatment decision-making and had decreased anxiety and depression at 6 weeks following consultation.

In another investigation, Onel et al³³ identified 111 men with newly diagnosed localized prostate cancer. The men, who were 48 to 83 years of age and were patients in four physician practices, initially met with their urologists and discussed personal PSA values and biopsy and staging results. Following the presentation of treatment options, which included radical prostatectomy, radiotherapy, and watchful waiting, the men completed a baseline survey and then viewed a 45-minute videotape. The videotape provided detailed information on risks and benefits of available treatment options and described possible outcomes. Information on the videotape was tailored according to patient risk category as defined by Gleason grade (ie, 2 to 4, 5 to 7, and 8 to 10) and patient age (ie, 55 to 65 and 66 to 75 years). A postvideo survey was completed. Analyses of survey data showed that there were significant increases in patient understanding of treatment options.

Conclusions

Decision aids for patients have taken the form of informational booklets, scripted telephone counseling, decision boards, educational videotapes, interactive videodiscs, computer programs, and Internet Web sites. They have been developed for use in relation to a variety of situations (eg, use of alpha blockers in the treatment of benign prostatic hyperplasia [BPH], surgery for BPH, adjuvant therapy for axillary node-negative breast cancer patients, antithrombotic therapy for stroke prevention in atrial fibrillation, hormone replacement therapy for postmenopausal women, and participation in clinical trials for women who are diagnosed with breast cancer).³⁴⁻⁴⁰ Examples of decision aids that have been developed in relation to prostate cancer early detection and treatment are outlined above. In the future development and evaluation of such tools, it is important to ensure that the educational content that is provided effectively addresses issues that are relevant and salient to potential users.

Chan and Sulmasy⁴¹ have conducted extensive focus group research to identify issues of concern to older adult men who are considering whether or not to have a prostate cancer early detection examination. They outlined specific content they believe to be appropriate for inclusion in decision aids. At a minimum, they recommend that men should be advised that false-positive and false-negative results may occur and that it is not known whether PSA testing reduces prostate cancer mortality. They also suggest

that information about the pros and cons of prostate cancer early detection should be provided. Myers et al⁴² have argued that educational messages should include the follow-up of abnormal prostate cancer early detection examination results. Message content should be tailored to patient education level, perceived self-efficacy, the belief that prostate cancer screening should be addressed in a timely fashion, belief that prostate cancer can be cured, and perceived physician support.

Feldman-Steward et al⁴³ identified 56 patients who were newly diagnosed with early prostate cancer within the previous year. A survey questionnaire was mailed to the men in order to identify the most important questions that prostate cancer patients would want to have answered. A total of 93 items, which were compiled from discussions with cancer patients, well lay people, oncologists, urologists, and health care researchers, were included on the survey. Thirty-eight men (68%) responded. There was agreement among respondents that it was essential for patients to be provided information about the nature of prostate cancer and its etiology, treatment options that are available should initial intervention fail, mechanisms whereby therapeutic interventions are known to work, likely impact of treatment impact on continence and sexual functioning, and the chances of cure.

In a national survey conducted in Canada, prostate cancer patients indicated that they did not fully comprehend information that they received about their stage of disease and different treatment options and were not satisfied with the supportive care they received.⁴⁴ Elsewhere, Iscoe et al⁴⁵ advised that it would be helpful to expand the range of medical care topics for discussion to include standard, experimental, and complementary alternative therapies. Findings from the Canadian survey and from other studies⁴⁶⁻⁵¹ indicate that concerns related to sexual dysfunction, impotence, pain, mood, and fatigue should be addressed in educational messages concerning prostate cancer treatment and recovery.

Coley et al⁵ have observed that the optimal way to provide effective preparatory education for informed decision-making is not yet known. Preparatory education provided in conjunction with use of tailored decision aids may be extremely useful in facilitating informed decision-making about prostate cancer early detection, treatment, and recovery. More research is needed to develop effective preparatory education messages and decision aids in the context of growing access to technologies. This effort should be

guided by a clear understanding of the concerns that men and their supportive others have about the specific situations that they face at different points along the continuum of prostate cancer care. In developing these modalities, attention should be paid to the matter of reaching patient populations that display a wide range of literacy levels and numeracy skills.⁵² Rigorous evaluation is necessary to assess the impact of these approaches on knowledge, attitudes, behavior, and clinical outcomes. Effective preparatory education approaches and decision aids should be disseminated broadly for use by practitioners with their patients.

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Special Articles

Biopsychosocial Aspects of Prostate Cancer

ELISABETH J.S. KUNKEL, M.D., JENNIFER R. BAKKER
RONALD E. MYERS, PH.D., OLU OYESANMI, M.D.
LEONARD G. GOMELLA, M.D.

Prostate cancer early detection choices and treatment options are fraught with controversy. To update the consultation-liaison psychiatrist who works with at-risk men, the authors reviewed all pertinent citations in the medicine database from 1966 to 1998 and in other relevant publications. Though watchful waiting for early-stage prostate cancer has no side effects, men must cope psychologically with issues of long-term cancer survivorship. Men can choose between different treatment options (e.g., radiation vs. radical prostatectomy) with early detection. Urinary incontinence, sexual dysfunction, and fatigue are major emotional and physical stressors for this population. Consultation-liaison psychiatrists and physicians need to be aware of the psychosocial sequelae of both prostate cancer and treatment-related side effects. (Psychosomatics 2000; 41:85-94)

BIOPSYCHOSOCIAL ASPECTS OF PROSTATE CANCER

Although fear, anger, confusion, and depression are common reactions to all cancers, treatment for prostate cancer means dealing with impotence and incontinence. The biopsychosocial model¹ is reviewed as it applies to prostate cancer.

Epidemiology

In the United States, prostate cancer is the most frequently diagnosed non-skin cancer and the second leading cause of cancer death in men. The American Cancer Society estimates 184,500 newly diagnosed cases of prostate cancer for 1998, with 39,000 deaths. The lifetime risk of prostate cancer is about 10%. White men survive longer than African American, Hispanic, and American Indian men, but survival rates for different races are similar when corrected for grade and stage. The stage at diagnosis predicts 5-year disease-specific survival rates: local stage dis-

ease, 100%; regional stage, 94%; and metastatic disease, 31%.²

Although African American men are twice as likely as white men to get prostate cancer, African American men in Philadelphia do not perceive their personal risk of prostate cancer to be high.³ Only some studies reveal differences in the frequency of digital rectal exam (DRE) screening between African American men and white men.⁴ African American men are more likely to be diagnosed at later stages, and men 65-69 years old, with localized disease, are less likely to be treated via radical prostatectomy (RP).⁵

In one study, non-private patients were less likely to receive prostate-specific antigen (PSA) screening.⁴ Lower socioeconomic groups are less willing than middle socioeconomic groups to participate in clinical trials because of

Received May 21, 1999; accepted September 14, 1999. From Departments of Consultation-Liaison Psychiatry, Internal Medicine, and Psychiatry and Human Behavior, Jefferson Medical College; and the Department of Urologic Oncology, Kimmel Cancer Center, Jefferson Medical College. Address reprint requests to Dr. Kunkel, Department of Psychiatry and Human Behavior, Thompson Building, Suite 1652, 1020 Sansom Street, Philadelphia, PA 19107-5000.

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Prostate Cancer

distrust of the medical community.^{6,7} RP is used more commonly in younger men (<60 years), and radiotherapy (RT) or watchful waiting is mostly used in older men (>70 years). Married men tend to be diagnosed earlier. Not surprisingly, survival rates are higher in married men from higher socioeconomic strata.⁸

Perceived discomfort of prostate screening, embarrassment, and financial cost have been identified as barriers to screening and need to be addressed by sensitive counselors.⁹ Churches consisting of predominantly African American members, and work sites may be effective sites for prostate cancer screening and education.¹⁰ Patients, particularly poorer African Americans, may opt to forgo needed care in the absence of available and affordable means of transportation to treatment facilities. Healthcare providers need to work with patients, families, and volunteer agencies in the community to enhance transportation to cancer treatment.¹¹ Although racially and culturally sensitive educational outreach programs need to provide education about prostate cancer and reduce barriers to early detection of prostate cancer among African American men, the relationship between access to care and prostate cancer outcome remains unclear.¹²

BIOLOGICAL ASPECTS

Anatomy and Physiology

The prostate gland surrounds the urethra, and prostatic secretions make up part of the seminal fluid.¹³ The hypothalamus secretes luteinizing hormone-releasing hormone (LHRH), which stimulates luteinizing hormone (LH) release from the pituitary. LH stimulates the testicular production of testosterone, which is turned into dihydrotestosterone, which stimulates prostatic cell growth and intracellular protein synthesis. PSA is produced both by benign and cancerous prostatic cells and released into the circulation. Prostate cancer metastasizes through blood or lymph to the pelvic nodes and then to distant sites.¹⁴

Staging and Grading

The TNM (Tumor, Node, Metastasis) system of the American Joint Committee on Cancer is identical to the classification system of the Union Internationale Contre le Cancer and is widely accepted. Most prostate cancers are adenocarcinomas; grade determination is based on the histopathological degree of cell differentiation and is often reported as a Gleason score (2 = very well differentiated to

10 = poorly differentiated). Lower Gleason scores are better.

Risk Factors

The cause of prostate cancer is unknown. Possible risk factors include African American race, increased age, family history of prostate cancer, a diet high in animal fat, and high plasma testosterone.¹⁵ Occupations associated with increased risk include printers, painters, rubber workers, textile workers, mechanics, loggers, ship fitters, farmers, and drug and chemical workers.¹⁶ Vasectomy and benign prostatic hyperplasia (BPH) do not appear to increase one's risk.¹⁷

Nutritional factors appear to play a role in the progression rate of prostate cancer.¹⁸ Vitamin D deficiency, polyunsaturated fats, and saturated fats may increase the risk of prostatic cancer; monounsaturated fats may be protective. Selenium supplements and lycopene, an antioxidant found in tomatoes,¹⁹ may lower the risk of prostate cancer. Vitamin E may reduce the incidence of prostate cancer in men who smoke.²⁰

In rare instances, prostate cancer is inherited by autosomal dominant allele with high penetrance; 88% of carriers and 5% of noncarriers develop prostate cancer by age 85.²¹ Men with HPC1 (hereditary prostate cancer 1) have a 90% risk of developing prostate cancer in their 90s.²² Male carriers of the BRCA1 (breast cancer 1) mutation are at three times greater risk than the general population. Receiving BRCA1 results impacts on quality of life, insurance, employment, and psychosocial well-being, but the health benefits of BRCA1 testing are unknown. Currently, there are no prostate cancer screening recommendations for men who are BRCA1 carriers.²³

Clinical Diagnosis

Many patients with prostate cancer are asymptomatic at diagnosis; others report dysuria, urinary frequency, hematuria, dribbling, decreased force of the urinary stream, incomplete bladder emptying, and/or nocturia. Metastatic disease may present with pain in the back, hips, or perineal area; bowel or urethral obstruction; or weight loss and fatigue.¹⁶

Screening

PSA is the most sensitive marker for prostate cancer. Uncommonly, it is possible to have a normal PSA level

(<4.0 ng/ml) and still have prostate cancer. A rise of PSA >0.75 ng/ml per year or a total PSA >4 ng/ml is associated with increased likelihood of cancer. Many men with BPH have PSA concentrations ranging from 4.1 to 10 ng/dl. Higher PSA concentrations (>10 ng/ml) have been associated with cancer as well as BPH, prostatitis, prostate infections, DRE, cystoscopy, transrectal ultrasonography, indwelling urinary catheters, transurethral resection of the prostate (TURP), and biopsy of the prostate. The clinician should aggressively investigate a PSA >10 ng/ml to rule out malignancy.²⁴

A rising PSA level after treatment indicates recurrent disease. Lower levels of free PSA and higher levels of circulating PSA (i.e., bound plus free PSA) are more likely to be associated with prostate cancer.¹⁹ Reverse transcriptase polymerase chain reaction is a highly specific research assay, which may be used in the future for staging, prognosis, and management.²⁵ The newest tests include prostate-specific membrane antigen, telomerase, and prostate markers.²⁶

The American Cancer Society recommends annual screening with PSA and DRE for asymptomatic men over 50 who are expected to live at least 10 years longer and for men over 40 who are at higher risk. Combined abnormal PSA and DRE has a greater positive predictive value than abnormal DRE alone. Screening of asymptomatic men remains controversial (see Table 1), and the U.S. Prevention Services Task Force, National Cancer Institute, and Canadian Task Force on the Periodic Health Examination do not recommend screening.^{2,23,24} If further testing is required after combined PSA and DRE, transrectal ultrasonography with transrectal biopsy typically follows; yet the true sensitivity of transrectal biopsy is not known. The

combined use of PSA, DRE, and ultrasound-guided biopsy may result in earlier detection, but there is no evidence from randomized trials that it reduces morbidity or disease-specific mortality. Biopsy may be associated with infection (20%), bleeding (20%), and hospitalization (<1%).¹⁵

Modifications in PSA measurement have included PSA density (serum PSA/volume of prostate gland), age-specific reference ranges, and PSA velocity (serial measurements of PSA).²⁴ Exercise and sexual activity may reduce the reliability of PSA-velocity in prostate cancer patients.²⁷ It is unclear if PSA velocity, PSA density, and age-specific reference ranges for PSA are better or not, compared to using standard PSA levels; in certain cases, however, they may provide additional information regarding early detection and treatment.

There is no way to distinguish between slow-growing tumors and clinically significant tumors.²⁶ Treatment may not reduce disease-specific mortality for tumors discovered incidentally. Although 30% of men over age 50 get prostate cancer, only 3% die from the disease. Aggressive treatment confers both morbidity and mortality.¹⁵ The downside of screening is increased psychological stress with repeated testing and/or diagnosis, treatment complications, reduced quality of life, and increased costs.¹⁵

Treatment

Treatment of prostate cancer depends on the patient's age, health, DRE, tumor stage, PSA levels, prostate biopsies, Gleason scores, and response to prior treatments for prostate cancer.²⁸ Accepted therapies include watchful waiting, RP, RT, hormonal therapy, orchiectomy, and antineoplastic drug therapy. There is no consensus regarding the relative survival benefits of different treatment modalities (see Table 2).

Localized prostate cancer may be managed by watchful waiting or may be treated with RP or RT. There are few published data on mortality in prospective, population-based studies for patients treated via RP or RT.²⁹ Watchful waiting may be most appropriate for older patients with

TABLE 1. Controversies of early detection with PSA testing

Advantages

- Will detect cancer early
- May detect cancer earlier than by DRE alone
- Early treatment may improve survival and avoid cancer complications
- Will reassure patient if normal
- Will give patient options to prevent spread of disease

Disadvantages

- May fail to detect cancer
- May cause anxiety related to testing and receiving test results
- May subject patient to further testing (e.g., biopsy)
- May subject patient to treatment-related complications
- Cannot distinguish between tumors that need treatment and tumors that are so slow-growing that without treatment, the patient is more likely to die of other noncancer causes
- Unclear whether detection reduces disease-related mortality
- Cost and whether reimbursed

TABLE 2. Ten-year prostate cancer-specific survival rates

Cancer Grade	Radical Prostatectomy	Radiotherapy	Conservative Management
I	94%	90%	93%
II	87%	76%	77%
III	67%	57%	45%

Note: Data adapted from Lu-Yao and Yao, 1997.²⁹

low-grade tumors, who have other serious medical problems that make them poor surgical candidates. In an asymptomatic patient, whose life expectancy is under 10 years, prostate cancer is unlikely to cause death. Disease progression is detected with periodic screening during watchful waiting, and treatment-related complications are avoided.³⁰ Patients may experience helplessness while not pursuing active treatment. They describe being "in limbo", waiting for their cancer to grow so that definitive treatment can begin.

RT may be used successfully for localized tumors. After treatment, a PSA level that falls below 0.5 ng/ml is associated with a better prognosis. External-beam irradiation requires visits (5 days/week for 8 weeks).³¹ Transperineal placement of radioactive seeds under ultrasound guidance is a relatively newer treatment; the seeds are left in place and emit local radiation for a short period of time.^{16,29,32} RT also may control pain from metastatic disease.

RP involves complete surgical removal of the prostate, seminal vesicles, ampullae of the vas deferens, the vas deferens, and the bladder cuff. One cannot compare the relative benefits of RP (which includes lymph node biopsy) vs. RT, where the extent of disease is not known.^{29,33} Because prostate cancer progresses slowly, more than 10 years may be needed to fully compare the effectiveness of RP vs. RT.²⁹

Both RP and RT confer similar risks: mortality (0.2%–0.3%), incontinence (0.8%–0.9%), and impotence (30%–70%) are the most common sequelae.³² Urinary leakage may be more common after RP than RT. Reports of pad usage after RP vary in the literature with the majority of men having minor or no urinary leakage by 6 months. Despite the newer "nerve sparing" techniques, many men may become impotent immediately after surgery.³⁴ Postoperative potency may be related to the number of spared neurovascular bundles, frequency of intercourse preoperatively, absence of seminal vesicle or lymph node involvement with cancer, absence of postoperative incontinence or stricture, age, and cancer volume.^{35,36} With RT, men may have a progressive loss over time in erectile function, suggesting that with time, posttreatment impotence may not differ significantly between men treated with RT vs. those treated with RP.³⁴ Gastrointestinal problems are more likely to be seen after RT.³¹

Locally advanced disease is treated with combinations of RP, RT, and hormonal therapy.^{16,29} Before surgery or RT, hormones may be used to reduce tumor size or to downstage the cancer. RT may be used with local tumor

recurrence. If PSA is elevated post-RP, therapeutic irradiation can achieve a complete response (PSA <0.1 ng/ml) in up to 80% of patients.³⁷

In advanced prostate cancer, therapy is aimed at disease control rather than cure. Asymptomatic patients may choose watchful waiting. Although hormonal treatment is preferred in symptomatic patients, it may not increase survival. Hormonal therapies include orchiectomy, estrogen use, or chemical castration via LHRH agonists. Bilateral orchiectomy removes 95% of serum testosterone and is a minor, low-cost procedure that eliminates the need for daily medication. Metastatic pain may be relieved within hours or days. Side effects include loss of libido and impotence. The psychological impact of orchiectomy may preclude the choice of this treatment option.^{16,32}

Orchiectomy may cause feminization, gynecomastia, redistribution of fat, loss of facial hair, sterility, and/or reduced libido.³⁸ Montgomery and Santi³⁹ noted significant differences in physical self-concept and identity before and after orchiectomy. Postoperatively, patients felt greater negativity in physical appearance, state of health, and sexuality. Patients expressed identity concerns and feared that a reduction in masculinity might lead to personality changes. Profound symbolic loss (as well as physical loss) after orchiectomy is experienced if the man associates his testicles with male strength, virility, and power.³⁹ The psychological effects of orchiectomy may be reduced with insertion of testicular prostheses.⁴⁰

Diethylstilbestrol (DES) reduces testosterone by negative feedback on LH. Daily therapy is required, and side effects include nausea, vomiting, fluid retention, headache, impotence, reduced libido, gynecomastia, and increased cardiovascular risk, including thromboembolic complications. Recently, LHRH analogues are replacing DES.¹⁶

LHRH analogues (e.g., leuprolide, goserelin) are taken daily or via long-acting injections and cause constant pituitary stimulation by occupying the LHRH receptors. Initially, they increase testosterone release, inducing tumor growth; if the tumor is located in the spinal cord, this growth can cause spinal cord compression. Side effects include impotence, loss of libido, and hot flashes.^{16,32} Concomitant use of an antiandrogen for the first 2 weeks of treatment may prevent the testosterone surge. Antiandrogens block androgen receptors and are either steroidal (progestin) or nonsteroidal (flutamide, nilutamide, bicalutimide). Total androgen blockade may be achieved using a combination of orchiectomy and/or antiandrogens. Androgen deprivation causes hot flashes, loss of libido, impotence, and decreased muscle mass.^{16,32} In hormone-refractory cancers,

various therapies including antineoplastic agents are used, with most agents showing poor response. Combination therapy may slow disease progression and increases survival compared to monotherapy, but this is controversial.

Hormonal castration usually tends to improve depression in patients with prostate cancer. As there is no threatened loss of body parts, patients describe feeling whole again and "embodied."⁴¹ However, increased depression also has been observed in some patients on hormonal therapy, perhaps linking depression to decreased testosterone. As one study has described depression secondary to leuprolide treatment in patients who had metastatic prostatic cancer, screening for depression may be warranted.⁴²

In advanced cancers, pain control should be assessed. Methods to control pain include wraps, pressure stockings, and heat in addition to opioids, steroids, nonsteroidal anti-inflammatory agents, antidepressants, and psychological support.^{16,32} Treatment, side effects, and quality-of-life (QOL) concerns often influence patients' decision-making regarding early detection and treatment.

PSYCHOLOGICAL ASPECTS

Patient education regarding screening is needed, since screening results in a high probability that further testing, treatment, and treatment-related decision-making will be necessary, particularly in high-risk groups.²⁶ If the patient has male relatives with prostate cancer, he may want a genetic test to determine his risk for prostate cancer.⁴³ Although African American men in Philadelphia are receptive to annual screening,⁴ there are still misconceptions about DRE (e.g., is something being inserted that will compromise [their] masculinity?). In one study, patients of low socioeconomic status showed less interest in PSA screening after informed consent. Videotaped educational interventions enhance patient knowledge and allow physicians to discuss more sophisticated patient concerns.⁴⁴ Faced with the diagnosis of a deadly disease, men simultaneously must confront threats to their sexuality and masculinity. Building rapport and trust during initial visits allows men to share their concerns. Survivors of prostate cancer must deal with treatment-related complications in the context of other age-related losses: health, energy, retirement, and deaths of peers and family members.

Patients with prostate cancer face several barriers to receiving appropriate psychiatric intervention. Cancers with sexual associations carry greater social stigma. North American men generally do not seek psychiatric help and tend to use mental health services less than women. Older

men may be less likely to agree to psychiatric evaluation or treatment and are unlikely to report emotional distress. Physicians tend to underestimate the psychological comorbidity of prostate cancer patients, and patients with subsyndromal psychiatric symptoms may remain untreated, even after identification. A paper thermometer scale to screen for psychological distress in prostate cancer patients, who might need psychiatric referral, detected a high degree of distress (32.6% anxiety and 15.2% depression). However, 40% of the distressed men missed or refused their psychiatric interview. Over half the men identified failed to meet the criteria for a psychiatric diagnosis.^{45,46}

Although there is increasing emphasis for men to assume a more active role in treatment decision-making, not all men may be comfortable with this role. Davison and Degner⁴⁷ studied whether improved information acquisition and assuming a more active role in treatment decision-making would lead to decreased anxiety and depression in men with newly diagnosed prostate cancer. Sixty newly diagnosed men with prostate cancer were randomized to receive either an intervention that consisted of written information with discussion, a list of questions to ask their physician, and an audiotape of the medical consult, or written information alone. At 6 weeks postintervention, lower state anxiety scores on the Spielberger State-Trait Anxiety Inventory were observed for the intervention group. The Center for Epidemiologic Studies Depression Scale (CES-D) did not reveal significant differences between the two groups.⁴⁷

Anxiety

Between 25% and 47% of cancer patients suffer from psychiatric syndromes. Reactive anxiety is the most common reason for psychiatric referral of cancer patients. Prostate cancer patients may react to the PSA test with anxiety, either before obtaining the test or while awaiting test results.⁴⁸ The degree of anxiety and depression experienced by cancer patients (prostate included) was not measurably different between different cancer sites (i.e., prostate, gynecologic, breast, lung, brain, colon, head and neck, hepatoma, and lymphoma) on the Brief Symptom Inventory.⁴⁹

Screening for prostate cancer is marked by increases in psychological stress and serum cortisol levels. The highest cortisol levels are detected 2 weeks after biopsy, just prior to being informed of the biopsy results. Even patients who were told that their biopsies were benign had elevated cortisol levels. Cortisol levels subsequently decreased to

Prostate Cancer

normal baseline values. Prostate cancer patients noted a lag in sleep disturbance, correlating with increased anxiety, 2 weeks after they were given their results.^{50,51}

Posttraumatic stress disorder (PTSD)-related symptoms also have been reported in prostate cancer patients.⁵² Patients may reexperience the traumatic events in dreams, disturbing recollections, and flashbacks.⁵³ Risk factors such as poor social support, a history of traumatization/victimization, or previous psychiatric disorder may predispose certain patients to PTSD. Cancer treatments are frequently intrusive and painful. Patients may feel a loss of control or experience helplessness in the face of life-threatening disease. In long-term cancer survivors, repeated treatments and/or recurrences may act as a series of stressors. While 25%–33% of all people who experience traumatic events develop PTSD, in one study, 4% of female cancer survivors had PTSD.⁵⁴ Although no specific PTSD treatment has been proposed for cancer patients with PTSD, cognitive-behavioral therapies and support groups may be beneficial.

Kornblith and colleagues⁵² studied 173 men with prostate cancer and 83 spouses/partners, using the Intrusion Subscale of the Impact of Event Scale and Selby's Quality of Life Uniscale. Both patients and spouses reported frequent intrusive thoughts and images. Spouses reported greater psychological distress than the patients. Prostate cancer patients exhibited no relationship between treatment severity or intensity and intrusive or avoidant symptoms.

Clark and colleagues⁵⁵ studied quality-of-life issues in men with metastatic prostate cancer and identified three key domains: self-perceptions; anxiety about the effects of treatment; and concerns about treatment decision-making. Many of the men reported anxious preoccupation or developing a fighting spirit in the face of their disease. Relationships with wives were altered. Though issues of intimacy and affection were troublesome for some men, impotence was emotionally distressing for most men. It was both difficult and comforting for spouses to emphasize emotional companionship. Body image, sexual problems, spouse affection, spouse worry, masculine image, cancer-related self-image, cancer distress, cancer acceptance, and regret over previously made decisions were areas of concern, particularly in men who had experienced many side effects.⁵⁵

Depression

Some sadness is not unusual when patients are diagnosed with prostate cancer. Physicians must distinguish be-

tween "normal" sadness in response to the cancer diagnosis and clinically significant depression.^{56,57} Issues such as cancer stage, clinical course, type of treatment, and presence of pain must be considered in evaluating depression.⁵⁸ Although 20%–25% of all patients with cancer may have a depressive disorder, depression often goes unrecognized. Neurovegetative symptoms may be due to the cancer or to the depression. Symptoms that differentiate the depressive illness from cancer include a sense of failure, social withdrawal, feelings of being punished, suicidal ideation, dissatisfaction, and indecision. Loss of interest and crying may present with more severe depression. Risk factors for depressive disorders include social isolation, recent losses, a tendency to pessimism, socioeconomic pressures, previous mood disorder, alcohol or substance abuse, previous suicide attempt, poorly controlled pain, depressive side effects of medication, and metastatic cancer. Psychotherapy, psychopharmacology, psychoeducation, and electroconvulsive therapy are all effective treatments for cancer patients with depression. Antidepressants with significant anticholinergic side effects should be avoided in patients with urinary retention or reduced intestinal motility.^{56,57,59,60}

Most individuals associate cancer with a slow, painful death.⁶¹ Patients with pain are more likely to suffer depression and anxiety, and Heim and Oei⁶² found that 55% of patients with prostate cancer reported pain. Analgesic drugs with lower side-effect profiles should be combined with adjuvant pharmacologic (e.g., antidepressants) and nonpharmacologic strategies, particularly in older patients.^{63,64}

Adjustment to Treatment-Related Side Effects

Physicians may underestimate the degree of emotional distress related to reduced libido, feeling unattractive, impotence, and incontinence. Although most impotence is treatment-related, for some men, psychogenic factors may be partly responsible, and psychiatric intervention may be important.⁶⁵ In the past, as most older adult men passed the traditional age associated with raising a family, less attention was paid to erectile function and the psychological consequence of impotence. However, older men are as likely to be disturbed by postsurgical impotence as younger men.⁶⁶ Etiology of erectile dysfunction after prostate cancer therapy is probably multifactorial. Arteriogenic impotence predominates among men undergoing RT. Venocclusive/cavernosal pathology predominates among men undergoing RP. Although most patients report problems in

sexual/urinary function, global quality of life does not appear to be compromised after RP.⁶⁷

Despite complaints of difficulty with erections, 60% of impotent patients did not use erectile aids (e.g., injections, vacuum devices) for 12 months or longer post-RP. Although impotency was a principal concern, most stated they would undergo surgery again for their peace of mind.⁶⁶ Sildenafil citrate (Viagra[®]) can reduce erectile dysfunction. It is administered orally, once daily, and is less invasive compared to cavernosal injection and implantation of penile prostheses. According to the manufacturer, 43% of men who had erectile dysfunction after RP achieved adequate sexual function with sildenafil citrate.⁶⁸ Men have to be sexually aroused for the drug to be effective. Side effects of sildenafil citrate include headache, flushing, dyspepsia, and visual disturbances. The use of organic nitrates is absolutely contraindicated in patients taking sildenafil citrate. Sixty-nine deaths have been associated with sildenafil citrate: 46 had cardiovascular events; 21, unknown; and 3 had strokes.⁶⁹

Men suffering from prostate cancer report impotence, fatigue, and incontinence as their primary concerns. Fatigue may be worsened by the increased demands of going for office visits and to the pharmacy. Incontinence (i.e., urine leakage, smelling of urine, and having to wear pads) leads to related demands to do more laundry and increased planning to be able to participate in social activities. After RP, some men may occasionally lose a few drops of urine when lifting heavy objects or coughing (i.e., stress incontinence). Other men are left with very little control over urine flow. Social isolation and embarrassment are understandable consequences.

SOCIAL ASPECTS

Until recently, prostate cancer had not received the same attention as other cancers in the popular press. Despite increasing numbers of published personal accounts of prostate cancer, the stigma of having cancer and potentially impaired sexuality may prevent patients from seeking adequate social and psychological support. Furthermore, there may be confusion between BPH and prostate cancer, leading men to underestimate the seriousness of the disease.

Men with prostate cancer receive assistance with household matters, emotional support, and encouragement from their spouses. However, spouses (and partners) show greater psychological distress than their husbands do, and this distress increases as the patient's condition worsens. It

is unclear if this reflects gender differences in reporting or truly greater stress induced by repeatedly witnessing intrusive, invasive, and painful treatments of a loved one while dealing with anticipatory bereavement.⁵² One study suggests that wives prefer early detection strategies for their spouses that offer increased survival at the expense of quality of life. Decision-making strategies clearly vary among couples.^{8,70}

Social support is positively correlated with psychological well-being, and low levels of social support correlate with increased mortality from all causes. Emotional support enhances self-esteem; informational support may provide advice or cognitive guidance. Social companionship provides contact with others and may provide a needed distraction from the stress of having cancer. Instrumental support can meet concrete needs by providing financial aid or material resources. Involvement in a social network can contribute to well-being by helping to develop feelings of predictability and stability. Social support buffering mechanisms for men are met through friendship, reassurance of worth, and reliable alliances. Companionship and task accomplishment adds to satisfaction. These social supports may translate into health benefits by positive influences on the functioning of neuroendocrine or immune systems, thereby acting as a buffer against disease. Other positive health-related effects include positive influences on behavior patterns (e.g., smoking and alcohol use).^{8,59,70,71}

Although it seems obvious that families caring for patients with prostate cancer are under emotional, physical, and financial strain, literature on prostate cancer caregivers is not available. Difficulties in communication and delays in care may result from inadequate knowledge or reluctance to ask about urologic needs or sexual symptoms. Dysfunctional and difficult families may find caregiving particularly overwhelming. Competent psychosocial intervention may help.⁴⁷

National support groups, such as "Us Too" and "Man to Man," can help meet the emotional and educational needs of prostate cancer patients.⁷¹ Interviews of some group members of Us Too and their primary care physicians revealed that although a high percentage of physicians recall discussing treatment options, side effects, and costs, a very low percentage of patients recall having had the same discussions. However, over 90% of both physicians and patients felt that the patient's own primary physician was a good source of cancer-related information. Both patients and physicians felt that physicians are less likely to provide emotional support. Support groups can

address unmet emotional and educational needs of prostate cancer patients and minimize suffering.⁷²⁻⁷⁴

Unfortunately, most survey instruments used to measure quality of life have not been standardized in this population, and complete data relating to QOL are absent in the literature. Reliable questionnaires that are prostate cancer-specific are being developed; however, physical function, pain, social activity, and sexual function are the most important areas of concern.⁷⁵ Most QOL studies include physical functioning, activities of daily living, and patient-reported sense of well-being. There have been some reports of physician resistance to measuring QOL. There is no consistency between which factors were measured by different instruments. QOL researchers suggest that problems in adaptation are seen most often in late-stage patients, who report greater pain, fatigue, and urinary difficulties.

Physicians often overestimate the level of physical functioning of a patient. Decreased sexual functioning, urinary incontinence, and bowel symptoms need to be considered in evaluating QOL. Some men trade long-term survival for potency; others avoid decreased sexual potency at all costs. Personality, motivation, a strong support system of family and friends, favorable environmental factors such as living in a first-floor apartment, having access to a pharmacy and other stores, and appropriate medical care are all important determinants of QOL.^{52,76-79} Some indicators that are used to measure QOL are body image, sexual problems, spousal affections, spousal worry, masculinity, cancer-related self-image, cancer distress, cancer acceptance, and regret of treatment decisions.⁸⁰ Self-perceptions, anxiety regarding treatment effects, and decision-making are equally important domains. Preservation of QOL at the expense of survival requires a clear understanding of what this trade-off entails.⁸¹ Quality-adjusted survival rates may not be appropriate to use in determination of treatment plans because of variations in individual values. It may be unreasonable to base treatment expectations on a return to the patient's premorbid level of functioning.

Because there is no therapy that is clearly superior for all patients and because all treatments carry risks of side effects, QOL considerations become increasingly impor-

tant in decision-making models. Often patients are faced with complex decisions that need to be made within a moderate time frame and for which patients are ill-prepared. Recent studies have attempted to incorporate educational programs into standard office visits. Determination of patient treatment preferences, using various decision-making aids, may facilitate decisions regarding early detection and treatment.⁸² Development of screening and treatment programs is hindered by lack of consensus regarding optimal methods of detection and treatment for prostate cancer. Even Medicare does not reimburse PSA screening. One study of 21 large managed care organizations indicated that they felt PSA testing was not mandatory; no treatment policy was in place for any of the managed care companies surveyed.⁸³

CONCLUSION

Men undergoing early detection for prostate cancer experience uncertainty related to the time course of cancer and often fear treatment and treatment-related side effects. It is still unclear whether early detection can reduce disease-specific mortality, and therein lies the controversy about early detection. Healthcare providers need to consider patient and family beliefs in the context of ethnocentric values. Although most patients are able to adapt to the cancer diagnosis and its management, QOL and treatment complications should be discussed by physicians who can counsel patients in the selection of preferred courses of treatments. Treatment choices are made more difficult by the lack of information on the long-term relative effectiveness of RP vs. RT.

Ideally, the management of anxiety and depression requires a multidisciplinary and multimodal approach. Psychiatrists can assist as diagnostic consultants in monitoring adjuvant psychotropic medications and in providing appropriate psychotherapy for treatment for men with prostate cancer and their families. An understanding of the current controversies in early detection and treatment can assist the C-L psychiatrist in working through difficult medical decisions with their patients.

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Communicating Effectively With the Patient and Family About Treatment Options for Prostate Cancer

Elisabeth J.S. Kunkel, MD, Ronald E. Myers, PhD, Philip L. Lartey, MD, and Olu Oyesanmi, MD

To help the patient with prostate cancer, his family, and his friends, in coping with the diagnosis and its treatment, health care providers need to understand the controversies about treatment options and the impact that such controversies have on medical decision-making. To update health care providers, the authors reviewed all pertinent citations in the medicine database from 1966 to 2000, and in other relevant publications. These resources are also available to our patients through the Internet and other avenues, such as books and magazines. It is the role of the physician to counsel patients about their individual circumstances to allow them to make the best individualized treatment option. Patients who have appropriate information and are actively involved with the decision-making process are, in general, psychologically healthier. Though watchful waiting has no side effects, men must cope psychologically with issues of long-term cancer survivorship. With early detection, men can choose between different treatment options (eg, radiation versus radical prostatectomy). Urinary incontinence, sexual dysfunction, and fatigue are major emotional and physical stressors for this population. Providers of care need to be aware of the psychosocial sequelae of prostate cancer and treatment-related side effects and assist their patients in processing ever-growing data on the management of prostate cancer that technology brings. Copyright © 2000 by W.B. Saunders Company

Key words: Prostate cancer, psychosocial, depression, anxiety, quality of life.

While fear, anger, confusion, and depression are common reactions to all cancers, treatment for prostate cancer means dealing with impotence and incontinence. The biopsychosocial model¹ is discussed, as a guide for helping providers to deal with patients with prostate cancer and their families. This challenge is further amplified because information access on the part of the patient and family can often be overwhelming.

Epidemiology

White men survive longer than African American, Hispanic, and American Indian men with prostate cancer, but survival rates for different races are simi-

lar when corrected for grade and stage.² African American men are twice as likely as white men to get prostate cancer and are more likely to be diagnosed at later stages. African American men who are 65 to 69 years old, with localized disease, are less likely to be treated with radical prostatectomy (RP).^{3,4} RP is used more commonly in younger men (<60 years), and radiotherapy (RT) or watchful waiting is mostly used in older men (>70 years). Married men tend to be diagnosed earlier with prostate cancer. Lower socioeconomic groups are less willing than middle socioeconomic groups to participate in clinical trials because of their distrust of the medical community. Not surprisingly, survival rates are higher in married men from higher socioeconomic strata.⁵⁻⁷

Biological Aspects

Risk Factors

Possible risk factors for prostate cancer include African American race, increased age, family history of prostate cancer, a diet high in animal fat, and high plasma testosterone. Occupations associated with increased risk include printers, painters, rubber workers, textile workers, mechanics, loggers, ship fitters, farmers, and drug and chemical workers. Vasectomy and benign prostatic hyperplasia (BPH) do not appear to increase one's risk.⁸⁻¹⁰

Nutritional factors appear to play a role in the progression rate of prostate cancer. Vitamin D defi-

From the Departments of Psychiatry and Human Behavior, and Internal Medicine, Jefferson Medical College; and the Department of Psychiatry, Albert Einstein Medical Center, Philadelphia, PA.

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Address reprint requests to Elisabeth J.S. Kunkel, MD, Department of Psychiatry and Human Behavior, Thomson Bldg, Suite 1652, 1020 Sansom St, Philadelphia, PA 19107-5000.

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ciency, polyunsaturated fats, and saturated fats may increase the risk of prostatic cancer; monounsaturated fats may be protective. Selenium supplements and lycopene, an antioxidant found in tomatoes, may lower the risk of prostate cancer. Vitamin E may reduce the incidence of prostate cancer in men who smoke.¹¹⁻¹³

In rare instances, prostate cancer is inherited by autosomal-dominant allele; 88% of carriers and 5% of noncarriers develop prostate cancer by age 85 years. Men with hereditary prostate cancer (HPC1) have a 90% risk of developing prostate cancer in their 90s. Male carriers of the breast cancer 1 (BRCA1) mutation are at three times greater risk than the general population. Receiving BRCA1 results impacts on quality of life, insurance, employment, and psychosocial well-being, but the health benefits of BRCA1 testing are unknown.¹⁴⁻¹⁶

In some studies, complementary and alternative therapies have been used to treat prostate cancer. Herbal therapies like PC-SPES* have important biologic activities, such as decreasing the serum concentrations of testosterone and PSA; however, PC-SPES may interfere with conventional treatment. The benefit of herbs must be balanced against clinically significant adverse effects.¹⁷⁻²⁰

Clinical Diagnosis

Most patients with prostate cancer are asymptomatic at diagnosis; others report dysuria, urinary frequency, hematuria, dribbling, decreased force of the urinary stream, incomplete bladder emptying, and nocturia. Metastatic disease may present with pain in the back, hips, or perineal area; bowel or urethral obstruction; weight loss and fatigue.⁹ There is no way to distinguish between slow-growing tumors and clinically significant tumors.²¹ Treatment may not reduce disease-specific mortality for tumors discovered incidentally. Although 30% of men over 50 years old get prostate cancer, only 3% die of the disease. Aggressive treatment confers both morbidity and mortality.⁸

Treatment

Treatment of prostate cancer depends on the patient's age, health, digital rectal examination, tumor

stage, PSA levels, prostate biopsies, Gleason scores, and response to prior treatments for prostate cancer.²² Accepted therapies include watchful waiting, RP, RT, hormonal therapy, orchiectomy, and anti-neoplastic drug therapy. There is no consensus regarding the relative survival benefits of different treatment modalities. Patients can often obtain conflicting information from publications, web sites, and support groups. Faced with the diagnosis of a deadly disease, men simultaneously must confront threats to their sexuality and masculinity. Building rapport and trust during initial visits allows men to share their concerns. Survivors of prostate cancer must deal with treatment-related complications in the context of other age-related losses: health, energy, retirement, and deaths of peers and family members.

Patients with prostate cancer face several barriers to receiving appropriate psychiatric intervention. Cancers with sexual associations carry greater social stigma. North American men generally do not seek psychiatric help and tend to use mental health services less than women.²³ Whereas women feel better when they can express their feelings, men feel better when they can participate in the medical treatment decision-making process; they prefer not to overburden their families.²⁴ Older men may be less likely to agree to psychiatric evaluation or treatment and are unlikely to report emotional distress. Physicians tend to underestimate the psychological comorbidity of prostate cancer patients, and patients with subsyndromal psychiatric symptoms may remain untreated, even after identification. Roth and others described a paper thermometer scale to screen for psychological distress in prostate cancer patients, who might need psychiatric referral, detecting a high degree of distress (32.6% anxiety and 15.2% depression). However, 40% of the distressed men missed or refused their psychiatric interview. More than half of the men identified failed to meet the criteria for a psychiatric diagnosis.^{23,25}

Although there is increasing emphasis for men to assume a more active role in treatment decision-making, not all men may be comfortable with this role. In 1997, Davison and Degner²⁶ studied whether improved information acquisition and assuming a more active role in treatment decision-making would lead to decreased anxiety and depression in men with newly diagnosed prostate cancer. Sixty newly diagnosed men with prostate cancer were randomly selected to receive either an intervention that consisted of a written information with discussion, list of questions to ask their physician, and an audiotape of the

* PC-SPES is an estrogenic herbal combination consisting of eight herbs: saw palmetto, scutellaria (skullcap), *Ganoderma lucidum*, panax pseudo-ginseng, chrysanthemum, licorice, *Rabdosia rubescens*, and *isatis*.

medical consult, or a written information alone. At 6 weeks' post-intervention, lower state anxiety scores on the Spielberger State-Trait Anxiety Inventory were observed for the intervention group. The Center for Epidemiologic Studies Depression Scale (CES-D) did not reveal significant differences between the two groups.²⁶

Localized prostate cancer may be managed by watchful waiting or may be treated with RP or RT. There are little published data on mortality in prospective, population-based studies for patients treated via RP or RT.²⁷ Watchful waiting may be most appropriate for older patients with low-grade tumors, who have other serious medical problems that make them poor surgical candidates. In an asymptomatic patient, whose life expectancy is less than 10 years, prostate cancer is unlikely to cause death. Disease progression is detected with periodic screening during watchful waiting, and treatment-related complications are avoided.²⁸ Patients may experience helplessness while not pursuing active treatment. They describe being "in limbo," waiting for their cancer to grow so that definitive treatment can begin.

RT may be used successfully for localized tumors and does not include a lymph-node dissection to determine the extent of disease (unlike RP). External beam irradiation requires visits, 5 days/week, for 8 weeks.²⁹ With transperineal placement of radioactive seeds under ultrasound guidance, the seeds are left in place and emit local radiation for a short period of time.^{9,27,30}

RP involves complete surgical removal of the prostate, seminal vesicles, ampullae of the vas deferens, the vas deferens, and the bladder cuff. It includes lymph-node biopsies, and so the outcome from RP cannot be compared with RT.^{27,31} Because prostate cancer progresses slowly, more than 10 years may be needed to fully compare the effectiveness of RP versus RT.²⁷

Both RP and RT confer similar risks; mortality (0.2% to 0.3%), incontinence (0.8% to 0.9%), and impotence (30% to 70%) are the most common sequelae.³⁰ Urinary leakage maybe more common following RP than with RT. Reports of pad usage after RP vary in the literature with most men having minor or no urinary leakage by 6 months.³²

Despite the newer "nerve-sparing" techniques, many men may become impotent immediately after surgery. Postoperative potency may be related to the number of spared neurovascular bundles, frequency of intercourse preoperatively, absence of seminal vesicle or lymph-node involvement with cancer, absence

of postoperative incontinence or stricture, age and cancer volume.³²⁻³⁴ With RT, men may have a progressive loss over time in erectile function, suggesting that with time, post-treatment impotence may not differ significantly between men treated with RT versus RP.³² Gastrointestinal problems are more likely to be seen after RT.²⁹ Specific authors may minimize or emphasize the clinical significance of different side effects secondary to RT versus RP. With patients reviewing the peer-reviewed literature on the Internet, their ability to critically evaluate the data presented may lead to false expectations with regards to outcome.

Although most impotence is treatment-related, for some men, psychogenic factors may be partly responsible and psychiatric intervention may be important.³⁵ In the past, as most elderly men had passed the traditional age associated with raising a family, less attention was paid to erectile function and the psychological consequence of impotence. However, older men are as likely to be disturbed by postsurgical impotence as younger men.³⁶ Etiology of erectile dysfunction after prostate cancer therapy is probably multifactorial. Arteriogenic impotence predominates among men undergoing RT. Veno-occlusive/cavernosal pathology predominates among men undergoing RP. Although most patients report problems in sexual/urinary function, global quality of life does not appear to be compromised following RP.³⁷

Despite complaints of difficulty with erections, 60% of impotent patients did not use erectile aids (eg, injections, vacuum devices) for 12 months or longer after RP. Although impotency was a principal concern, most stated they would undergo surgery again for their peace of mind.³⁶ Sildenafil citrate (Viagra; Pfizer, New York, NY) can reduce erectile dysfunction. It is administered orally, once daily, and is less invasive compared with cavernosal injection and implantation of penile prostheses. According to the manufacturer, 43% of men who had erectile dysfunction following RP achieved adequate sexual function with sildenafil citrate.³⁸ Men have to be sexually aroused for the drug to be effective. Side effects of sildenafil citrate include headache, flushing, dyspepsia, and visual disturbances. The use of organic nitrates is absolutely contraindicated in patients taking sildenafil citrate. Sixty-nine deaths have been associated with sildenafil citrate: 46 had cardiovascular events, 21 unknown, and 3 had strokes.³⁹

In advanced prostate cancer, therapy is aimed at disease control rather than cure. Asymptomatic patients may choose watchful waiting. Although

hormonal treatment (orchiectomy, estrogen use, or chemical castration) is preferred in symptomatic patients, it may not increase survival. Pain control should be assessed, as patients with pain suffer depression and anxiety.⁴⁰ Treatment, side effects, and quality-of-life concerns often influence patients' decision-making regarding treatment. Most individuals associate cancer with a slow, painful death.^{9,30,41}

Physicians may underestimate the degree of emotional distress related to reduced libido, feeling unattractive, impotence, and incontinence. Men suffering from prostate cancer report impotence, fatigue, and incontinence as their primary concerns. Fatigue may be worsened by the increased demands of going for office visits, to the pharmacy, etc. Incontinence (ie, urine leakage, smelling of urine, and having to wear pads) leads to related demands to do more laundry and increased planning to participate in social activities. Following RP, some men may occasionally lose a few drops of urine when lifting heavy objects or coughing (ie, stress incontinence). Other men are left with very little control over their urine flow. Social isolation and embarrassment are understandable consequences.

Psychological Aspects

Anxiety

Between 25% and 47% of cancer patients suffer from psychiatric syndromes. Reactive anxiety is the most common reason for psychiatric referral of cancer patients.⁴² The degree of anxiety and depression experienced by cancer patients (prostate included) was not measurably different between different cancer sites (ie, prostate, gynecologic, breast, lung, brain, colon, head and neck, hepatoma, and lymphoma) on the Brief Symptom Inventory.⁴³

Post-traumatic stress disorder (PTSD)-related symptoms also have been reported in prostate cancer patients.⁴⁴ Patients may reexperience the traumatic events in dreams, disturbing recollections, and flashbacks.⁴⁵ Risk factors, such as poor social support, a history of traumatization/victimization, or previous psychiatric disorder, may predispose certain patients to PTSD. Cancer treatments are frequently intrusive and painful. Patients may feel a loss of control or experience helplessness in the face of life-threatening disease. In long-term cancer survivors, repeated treatments or recurrences may act as a series of stressors. Although 25% to 33% of all people, who experience traumatic events acquire PTSD, in one study, 4% of

female cancer survivors had PTSD.⁴⁶ Although no specific PTSD treatment has been proposed for cancer patients with PTSD, cognitive-behavioral therapies, support groups, and pharmacotherapy may be beneficial.

Kornblith et al⁴⁴ studied 173 men with prostate cancer and 83 spouses/partners, using the Intrusion Subscale of the Impact of Event Scale, and Selby's Quality of Life Uniscale. Both patients and spouses reported frequent intrusive thoughts and images. Spouses reported greater psychological distress than the patients. Prostate cancer patients exhibited no relationship between treatment severity or intensity, and intrusive or avoidant symptoms.⁴⁴ Drug companies believe that providing prostate cancer education to spouses, daughters, and partners help motivate men to seek medical attention for prostate problems.²³

Clark et al⁴⁷ studied quality-of-life issues in men with metastatic prostate cancer and identified three key domains: self-perceptions, anxiety about the effects of treatment, and concerns about treatment decision-making. Many of the men reported anxious preoccupation or developing a fighting spirit in the face of their disease. Relationships with wives were altered. Though issues of intimacy and affection were troublesome for some men, impotence was emotionally distressing for most men. It was both difficult and comforting for spouses to emphasize emotional companionship. Body image, sexual problems, spouse affection, spouse worry, masculine image, cancer-related self-image, cancer distress, cancer acceptance, and regret over previously made decisions were areas of concern, particularly in men who had experienced many side effects.⁴⁷

Depression

Some sadness is not unusual when patients are diagnosed with prostate cancer. Physicians must distinguish between "normal" sadness in response to the cancer diagnosis and clinically significant depression.^{48,49} Issues, such as cancer stage, clinical course, type of treatment, and presence of pain, must be considered in evaluating depression.⁵⁰ Although 20% to 25% of all patients with cancer may have a depressive disorder, depression often goes unrecognized. Neurovegetative symptoms may be due to the cancer or to the depression. Symptoms, which differentiate the depressive illness from cancer, include a sense of failure, social withdrawal, feelings of being punished, suicidal ideation, dissatisfaction, and indecision. Loss of interest and crying may present with more severe

depression. Risk factors for depressive disorders include social isolation, recent losses, a tendency to pessimism, socioeconomic pressures, previous mood disorder, alcohol or substance abuse, previous suicide attempt, poorly controlled pain, depressive side effects of medication, and metastatic cancer. Psychotherapy, psychopharmacology, psychoeducation, and electroconvulsive therapy are all effective treatments for cancer patients with depression. Antidepressants with significant anticholinergic side effects should be avoided in patients with urinary retention or reduced intestinal motility.^{48,49,51,52}

Social Aspects

Until recently, prostate cancer had not received the same attention as other cancers in the popular press. Despite increasing numbers of published personal accounts of prostate cancer, the stigma of having cancer and potentially impaired sexuality may prevent patients from seeking adequate social and psychological support. Furthermore, there may be confusion between BPH and prostate cancer, leading men to underestimate the seriousness of the disease.

Men with prostate cancer receive assistance with household matters, emotional support, and encouragement from their spouses. However, spouses (and partners) show greater psychological distress than their husbands do, and this increases as the patient's condition worsens. It is unclear if this reflects gender differences in reporting, or truly greater stress, induced by repeatedly witnessing intrusive, invasive, and painful treatments of a loved one while dealing with anticipatory bereavement.⁴⁴ One study suggested that wives preferred early detection strategies for their spouses that offer increased survival at the expense of quality of life. Decision-making strategies clearly vary among couples.^{7,53}

Social support is positively correlated with psychological well-being, and low levels of social support correlate with increased mortality from all causes. Emotional support enhances self-esteem; informational support may provide advice or cognitive guidance. Social companionship provides contact with others and may provide a needed distraction from the stress of having cancer. Instrumental support can meet concrete needs by providing financial aid or material resources. Involvement in a social network can contribute to well-being by helping to develop feelings of predictability and stability. Social support buffering mechanisms for men are met through friendship, reassurance of worth, and reli-

able alliances. Companionship and task accomplishment adds to satisfaction. These social supports may translate into health benefits by positive influences on the functioning of neuroendocrine or immune systems, thereby acting as a buffer against disease. Other positive health-related effects include positive influences on behavior patterns (ie, smoking, alcohol use).^{7,51,53,54}

Although it seems obvious that families caring for patients with prostate cancer are under emotional, physical, and financial strain, literature on prostate cancer caregivers is not available. Difficulties in communication and delays in care may result from inadequate knowledge or reluctance to ask about urologic needs or sexual symptoms. Dysfunctional and difficult families may find caregiving particularly overwhelming. Competent psychosocial intervention may help.²⁶ In a recent study, it was noted that cancer patients expressed a desire to have access to someone who might be able to spend more time with them. They also expressed the need for continuity of care.⁵⁵

National support groups, such as "Us Too" and "Man to Man," can help meet the emotional and educational needs of prostate cancer patients. Interviews of some group members of "Us Too" and their primary care physicians revealed that although a high percentage of physicians recall discussing treatment options, side effects, and costs, a very low percentage of patients recall having had the same discussions. Notwithstanding, more than 90% of both physicians and patients believed that the patient's own primary physician was a good source of cancer-related information. Both patients and physicians believed that physicians are less likely to provide emotional support. Support groups can address unmet emotional and educational needs of prostate cancer patients and hopefully, minimize suffering.⁵⁶⁻⁵⁸ Cunningham et al⁵⁹ have shown that coping skills training in small support groups improves mood and quality of life in a broad range of cancer patients.

Unfortunately, most survey instruments used to measure quality of life have not been standardized in this population, and complete data relating to quality of life is absent in the literature. Reliable questionnaires that are prostate-specific are being developed; however, physical function, pain, social activity, and sexual function are the most important areas of concern.⁶⁰⁻⁶² Most quality of life studies include physical functioning, activities of daily living, and patient-reported sense of well-being. There have been some reports of physician resistance to measuring quality of life. There is no consistency between which factors

were measured by different instruments. Quality of life researchers describe that problems in adaptation are seen most often in late-stage patients, who report greater pain, fatigue, and urinary difficulties.

Physicians often overestimate the level of physical functioning of a patient. Decreased sexual functioning, urinary incontinence, and bowel symptoms need to be considered in evaluating quality of life. Some men trade long-term survival for potency; others avoid decreased sexual potency at all costs. Personality, motivation, a strong support system of family and friends, favorable environmental factors such as living in a first floor apartment, having access to pharmacy, other stores, and appropriate medical care are important determinants of quality of life.^{44,63-66} Patients, particularly poorer African American, may opt to forgo needed care in the absence of available and affordable means of transportation to treatment facilities. Health care providers need to work with patients, families, and volunteer agencies in the community to enhance transportation to cancer treatment.⁶⁷ Although racially and culturally sensitive educational outreach programs need to provide education about prostate cancer, the relationship between access to care and prostate cancer outcome remains unclear.⁶⁸

Some indicators that are used to measure quality of life are body image, sexual problems, spousal affections, spousal worry, masculinity, cancer-related self-image, cancer distress, cancer acceptance, and regret of treatment decisions.⁶⁹ Self-perceptions, anxiety regarding treatment effects, and decision-making are equally important domains. Preservation of quality of life at the expense of survival requires a clear understanding of what this trade-off entails.⁷⁰ Quality-adjusted survival rates may not be appropriate to use in determination of treatment plans due to variations in individual values. It may be unreasonable to base treatment expectations on a return to the patient's premorbid level of functioning.

Because there is no therapy that is clearly superior for all patients and because all treatments carry risks of side effects, quality of life considerations become increasingly important in decision-making models. Often, patients are faced with complex decisions, which need to be made within a moderate time frame and for which they were ill-prepared. Recent studies have attempted to incorporate educational programs into standard office visits. Determination of patient treatment preferences, using various decision-making aids, may facilitate decisions regarding early de-

tection and treatment.⁷¹ Development of treatment programs is hindered by lack of consensus regarding optimal treatment for prostate cancer. One study of 21 large managed care organizations indicated that no treatment policy was in place for any of the managed care companies surveyed.⁷²

Conclusions

Men who are diagnosed with prostate cancer experience uncertainty related to the time course of the cancer and often fear treatment and treatment-related side effects. Health care providers need to consider patient and family beliefs in the context of ethnocentric values. Although most patients are able to adapt to the cancer diagnosis and its management, quality of life and treatment complications should be discussed by physicians who counsel patients in the selection of preferred courses of treatments. Treatment choices are made more difficult by the lack of information on the long-term relative effectiveness of RP versus RT. Health care providers should be aware of the resources (eg, books, Web sites, support groups) that a given patient may be using to guide their decision-making process.

Ideally, the management of anxiety and depression requires a multidisciplinary and multimodal approach. Psychiatrists can assist as diagnostic consultants, in monitoring adjuvant psychotropic medications, and in providing appropriate psychotherapy for treatment for men with prostate cancer and their families. An understanding of the current controversies in early detection and treatment can assist the health care provider in working through difficult medical decisions with patients with prostate cancer and their families.

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Decision counseling for men considering prostate cancer screening

Matthew J. Liberatore^{a,*}, Ronald E. Myers^b, Robert L. Nydick^a,
Michael Steinberg^c, Earl R. Brown^d, Roy Gay^e, Thomas Powell^f,
Roberta Lee Powell^f

^a*Department of Decision and Information Technologies, Villanova University, 800 Lancaster Avenue,
Villanova, PA 19085, USA*

^b*Department of Medicine, Division of Genetic and Preventive Medicine, Behavioral Epidemiology Section,
Thomas Jefferson University, 1100 Walnut Street, Suite 400, Philadelphia, PA 19107, USA*

^c*School of Public Health, University of Medicine and Dentistry of New Jersey, 317 George Street, Suite 210,
New Brunswick, NJ 08901, USA*

^d*1335 W. Tabor Road, Philadelphia, PA 19141, USA*

^e*5301 Cedar Avenue, Philadelphia, PA 19143, USA*

^f*6013 Green Street, Philadelphia, PA 19144, USA*

Abstract

One in six men will develop prostate cancer in their lifetimes; and the risk of dying from the disease is elevated by a factor of at least two among African-American men. Many asymptomatic men who are diagnosed with prostate cancer have their disease detected through a prostate cancer screening examination. The examination often includes both a digital rectal examination and prostate-specific antigen testing. Although annual screening is recommended by several organizations, others urge caution since no randomized trials have demonstrated that screening can reduce mortality from prostate cancer. Concern about prostate cancer screening is also based on the fact that diagnosis and treatment of early-stage prostate cancer can cause substantial adverse outcomes. To facilitate shared decision making between the patient and medical practitioner, it is important to provide information that is needed to make an informed decision. In this paper, we discuss the development and implementation of a decision-counseling protocol for prostate cancer screening. This protocol, which incorporates the analytic hierarchy process (AHP), is designed as a decision aid for use in facilitating decision making about whether or not to have a screening examination. We discuss several modifications to the standard AHP that were required to fit the needs of the target population. The counseling protocol has been applied in randomized trials involving diverse populations. While health educators required some training to administer the decision-counseling protocol, none was needed for the patients. The results have demonstrated

* Corresponding author. Tel.: +1-610-519-4390; fax: +1-610-519-5015.

E-mail address: matthew.liberatore@villanova.edu (M.J. Liberatore).

that a well-designed decision-counseling protocol administered by a trained facilitator can be successfully implemented in a primary care patient population.

Scope and purpose

In this paper, we discuss the development and implementation of a decision-counseling protocol for prostate cancer screening. The protocol was developed by a multidisciplinary research team of which the authors are members. It consists of two components: an information booklet on prostate cancer and screening; and an AHP-based counseling session. Modifications to the standard AHP that were required to fit the needs of the target population are described. This decision-counseling protocol was successfully applied in four primary care settings, with preliminary findings reported for one of these.

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1. Introduction

In 2002, there will be more than 189,000 new cases of prostate cancer and an estimated 30,200 prostate cancer-related deaths in the United States [1]. Prostate cancer incidence and mortality increase with age and are substantially elevated in high-risk groups (e.g., African-American men and men who have a family history of prostate cancer) [2]. One in six men will develop prostate cancer in his lifetime; and the risk of dying from the disease is elevated by a factor of at least two among African-American men. From 1986 to 1993, the overall 5-year prostate cancer survival rate for African-American men was 75% and for white men it was 90% [3,4].

Many asymptomatic men who are diagnosed with prostate cancer have their disease detected through a prostate cancer screening examination. The examination often includes both a digital rectal examination (DRE) and prostate-specific antigen (PSA) testing. Proponents of prostate cancer screening believe that routine DRE and PSA testing is justified for men who have a reasonable life expectancy and is especially important for men who are at increased risk on the basis of race and family history [5,6]. They argue that combined DRE and PSA testing is effective in identifying men with early prostate cancer and that men who are diagnosed with and treated aggressively for localized prostate cancer have higher survival rates as compared to men diagnosed with late-stage disease [7,8]. The American Cancer Society and the American Urological Association recommend annual DRE and PSA testing for men who are 50 or more years of age [1,9]. The American Cancer Society also recommends that screening begin at age 45 for African-American men and those who have a family history of prostate cancer [9].

Caution has been urged regarding prostate cancer screening, however, because no randomized trials have demonstrated that screening can reduce mortality from prostate cancer [10,11]. Results of trials that are now underway will not be available for a decade or more [12–14]. Concern about prostate cancer screening is also based on the fact that diagnosis and treatment of early-stage prostate cancer can cause substantial adverse outcomes (e.g., impotence, incontinence, bowel injury, and mortality) [15,16]. Guidelines put forward by the United States Preventive Services Taskforce and the Canadian Taskforce on the Periodic Health Examination recommend that DRE and PSA testing should not be performed to screen for early prostate cancer [17,18]. Most recently, the American College of Physicians has advised against the routine use of screening examinations for asymptomatic older adult

men, irrespective of risk status. Rather, the delivery of information concerning the potential benefits and harms of screening, follow-up, treatment and the provision of assistance in decision making are both encouraged [19]. Unfortunately, few tools are available to help practitioners implement these guidelines.

Today, individuals are being asked to assume an increasing level of responsibility for decision making about personal health care [20]. Patients are now expected to act as partners with health care professionals to engage in shared decision making [21] about health-related issues. This shared decision-making paradigm is ideal, that is supplanting the more traditional model in which the medical practitioner assumes responsibility for choosing a health care strategy that is in the best interests of the patient. To facilitate shared decision making, it is important to provide information that is needed to make informed decisions, enable patients to recognize the importance and legitimacy of their role in medical decision making, understand the implications of choosing from among different health care alternatives, and consider their personal values and preferences related to the choices at hand.

In this paper, we discuss the development and implementation of a decision-counseling protocol for prostate cancer screening. This protocol, which incorporates the analytic hierarchy process (AHP), is designed as a decision aid for use in facilitating decision making about whether or not to have a screening examination.

2. Decision aids and prostate cancer screening

Information to help people make decisions about preventive health care and treatment of disease has been delivered using a variety of modes that have been described as decision aids. Patients have used informational brochures, educational videotapes, interactive videodiscs, and sites on the Internet in the absence of direct interaction with a health care practitioner. Other modes facilitate immediate, personal interactions between practitioners and patients (e.g., formatted print and verbal descriptions, and decision boards, which are charts showing the likelihood of different events).

The literature on decision aids suggests that, in general, the aids are well accepted by patients when they can be accessed easily. In addition, they tend to increase patient knowledge, provoke little or no patient anxiety, reduce decisional conflict, and foster interactions between practitioners and patients relative to decision making. It also appears that exposure to decision aids may improve patient outcomes (e.g., side effects, role functioning, physical functioning, and general health) [22]. Recent reviews of research into decision aids have called for the use of rigorous research designs that are based on theory, include meaningful process and outcome measures, and serve to identify interventions that can facilitate practitioner–patient interaction [23,24]. With respect to prostate cancer screening, Coley et al. [25] observed that there are no published data that indicate the best way to enable individuals to consider systematically available information about screening decision making, weigh the pros and cons of behavioral alternatives, and make informed decisions about preventive care on the basis of personal values. Similarly, Ubel [26] observed that, while several methods have been used to make information about prostate cancer screening available (e.g., brochures, videos, decision boards), little is known about their impact on knowledge, attitudes, and behavior. Research in this area is increasing, however.

Wolf et al. [27] published results of a study involving older adult men who presented at a primary care physician office for an outpatient appointment. Men who were exposed to a detailed description of the pros and cons of prostate cancer screening were less likely to be interested in having an exam than those who were exposed to a brief statement that the exam was available. In another study reported in the same article, older adult men who visited a general internal medicine clinic were randomly assigned either to an intervention group that viewed a videotape, which described prostate cancer screening in cautionary terms, or to a control group. Intervention group men were much less likely to have a prostate cancer screening examination than control group men. It is likely that the equivocal nature of the more intensive educational messages discouraged men from having an exam.

Flood et al. [28] investigated the prostate cancer knowledge and screening likelihood for men who attended a free PSA screening clinic and those who were seen for a routine outpatient appointment. They found that an educational videotape regarding prostate cancer screening improved patient knowledge about prostate cancer and screening. Men who saw the videotape in the routine appointment setting also were less likely to have PSA screening than men who did not. This result did not hold for the men attending the free PSA screening clinic.

In an urban community study conducted in Michigan, media announcements were used to recruit men to undergo prostate cancer screening with DRE and PSA testing [29]. Men completed a baseline survey questionnaire at the screening site, viewed an educational videotape, and filled out an exit survey. At baseline, African-American men were significantly less knowledgeable about prostate cancer and screening than men who were not African-American. At the exit survey, there was no longer a race-related knowledge difference.

Volk et al. [30] reported on a study concerning the prostate cancer knowledge of 160 men who were 45–70 years of age and who presented at a university-based family medicine clinic for scheduled office visits. Men who completed a baseline survey were assigned to either a control group or an intervention group. Those men in the intervention group were shown a 20-min videotape that presented information on the pros and cons of PSA testing. Two weeks after the office visit, an end-point survey was administered. Intervention group men provided more accurate responses to survey items that concerned early prostate cancer mortality rates, performance characteristics of PSA testing, and treatment-related complications as compared to control group men. The authors concluded that exposure to the videotape decision aid enhanced the capacity of study participants to make an informed decision about having a prostate cancer screening exam.

Frosch et al. [31] used the same videotape described above in Volk et al. [30]. The authors compared the effectiveness of three interventions to promote shared decision making about prostate cancer screening among men seen in a preventive health program. The three interventions were: a videotape alone, an oral presentation and discussion, and a videotape with a question and answer session. These interventions were compared with men who received no intervention (usual care). All three interventions improved knowledge regarding prostate cancer screening, reduced enthusiasm for screening, and increased interest in participating in screening decisions. All three interventions also significantly decreased the proportion of men who chose to have PSA screening; the magnitude of the reduction was significantly greater in the two groups who saw the videotape than in the discussion only group.

In a randomized controlled trial involving 257 men seen at a Department of Veterans' Affairs Hospital in Milwaukee, Schapira and VanRuiswyk [32] found that an illustrated pamphlet

describing the possible outcomes of prostate cancer screening increased knowledge about prostate cancer screening but had no effect on whether or not the men had the test.

Myers et al. [33] randomly assigned 413 African-American men who were 40–70 years of age either to a minimal or enhanced intervention group. The former group received an introductory letter that invited them to visit a urology clinic to receive information about prostate cancer screening and to decide whether to have a screening exam (DRE and PSA testing). The latter group received the same contact plus a personally tailored informational booklet and a follow-up telephone contact related to prostate cancer screening. At the clinic, men from both groups were provided print materials that described the pros and cons associated with prostate cancer screening. If the participant chose to have an exam, he was asked to sign a written consent for testing. Results from the study showed that men in the enhanced intervention group were significantly more likely than men in the minimal intervention group to make a clinic visit and have a screening exam (51% and 29%, respectively).

Findings from the studies described above show that there are a number of different ways to convey information to patients about screening. These studies do not shed light on what practitioners can do, beyond simply providing information, to help patients make informed decisions about their health care.

3. Decision support methods for patient decision making

In selecting from available alternative courses of action, individuals are influenced by the extent to which they believe that a given alternative will serve to achieve one or more criteria. Further, the overall perceived value of a given alternative is often based on the perceived likelihood of achieving multiple and sometimes conflicting criteria. The actual process of deciding on a given course of action usually includes the following steps: (1) identifying the alternatives available and the personal criteria on which they will be evaluated; (2) determining how well the alternatives achieve personally meaningful criteria, based on an assessment of available data and personal preferences; (3) determining the importance of each criterion in the decision-making process; and (4) making a choice among the alternatives after processing the information obtained in the previous steps [34].

There are a number of models that have been developed to aid decision making. These models include goal programming, multiobjective programming, scoring methods, multiattribute utility theory (MAUT), and the AHP [35,36]. Of these, we considered only the two most widely used approaches, namely MAUT and AHP. Both of these approaches have been successfully applied to medical decision making [37–44].

After a review of both methods, AHP was selected since the use of pairwise comparisons was thought to be a decision-making approach that simplifies the process of making judgments. In addition, another important practical advantage of AHP is that it allows and measures inconsistency of judgments. These advantages make AHP a decision-making approach that is more natural and accessible to individuals with diverse educational and social backgrounds.

4. Developing the decision-counseling protocol

In 1999, we assembled a multidisciplinary research team representing health education, social psychology, psychiatry, epidemiology, biostatistics, decision science, primary care, radiology, and

urology. The research team began developing a decision-counseling protocol that included two components: an informational booklet on prostate cancer and screening; and an AHP-based decision-counseling session. Both intervention components addressed pros and cons associated with prostate cancer screening.

4.1. Informational booklet

Specific items addressed by the booklet include: the differences of opinion relating to the value of a routine prostate checkup, the function of the prostate gland, risk factors for prostate cancer, prostate problems, the process for checking for prostate cancer, treatment options, and the value of making a personalized decision.

The informational booklet was field-tested in face-to-face interviews. A literacy expert from the Health Promotion Council of Greater Philadelphia conducted interviews with 20 local men between the ages of 40 and 69. The goal of the interviews was to determine if the men could recognize the purpose of the booklet and to learn if they understood the language, terminology, and concepts contained therein. Most men reported that the text was easy to read and interesting. However, it was suggested that the medical terminology be simplified and more pictures should be included. Interestingly, many men said that they thought the purpose of the booklet was simply to encourage prostate cancer screening. Many overlooked the central message in the booklet, that is, there is a decision to be made about screening. The interviewees also indicated that they would be likely to read the booklet and consider the issue of screening more carefully if they were encouraged to do so by their physician.

We modified the informational booklet by simplifying the text, making the issue of decision making more prominent, and including a page that makes physician support explicit. These and other changes were incorporated into a final version. This version highlights the screening controversy, provides information about prostate cancer and screening, clarifies steps involved in screening and diagnostic evaluation of abnormal findings, explains treatment options, and encourages shared decision making.

4.2. AHP-based, decision-counseling session

The research team also developed an AHP-based decision-counseling protocol that was designed for use by a health educator in a primary care setting. The team considered different modes for collecting and processing decision-making information. AHP-based decision support software is available but was not selected for this study for several reasons. First, the research team decided against using a personal computer in order to maintain the focus on the interaction between the health educator and the patient. We were concerned about positive and negative reactions to the presence of computer hardware. Second, errors in data entry could lead to additional time required to complete the session. Third, a general purpose AHP software package provides unneeded and potentially distracting functionality. As a result, tables were created that list all possible combinations of judgments along with their corresponding AHP weights. (The number of possible judgments was limited as discussed below.) These weights are then combined using a weighted-averaging approach to determine the patient's overall strength of preference toward having or not having an exam.

Initially, a paper and pencil system was devised and tested first with focus group participants and later with individual patients. Based on direct observation and patient feedback, it was apparent that

this approach required too much time to complete. A calculator-based approach was developed and demonstrated. It was decided that this approach was unobtrusive and easy to use.

Information provided by the focus groups indicated that it was necessary to modify and simplify several aspects of the standard AHP. Four areas required modifications.

- (1) Placing limits on the number of criteria and the number of alternatives to be evaluated.

The purpose of this modification is to minimize the required number of judgments that the patient must provide and to help reduce the likelihood of unacceptable levels of inconsistency. After extensive discussion, we decided to limit the number of criteria to three and the number of alternatives to two (have PSA/DRE exam versus do not have PSA/DRE exam). Having the patient rank the criteria as most important, second most important, and third most important also simplifies the process of eliciting the necessary judgments. For the same reason, the patient is asked to indicate which alternative favors each criterion. For example, suppose the patient indicated that maintaining his health state is an important decision criterion. He would then be asked: Would maintaining your health state lead you to have or not have the exam?

- (2) Truncating the AHP scale to better reflect the patient's strength of preference and to reduce the likelihood of inconsistency.

The standard AHP measurement scale is limited to one order of magnitude for expressing preferences of one item over another. Specifically, 1, 3, 5, 7, and 9 represent equal, moderate, strong, very strong, and extreme importance, respectively. A 9.9 can be used to indicate that one item completely dominates another.

When the number of criteria is limited to three and the number of alternatives to two (as mentioned in point 1 above), the alternative favoring the most important criterion will generally be the preferred alternative. Specifically, this situation will occur if the most important criterion is at least three times more important than the second most important criterion. Therefore, in these circumstances, we can effectively replace the 3, 5, 7, and 9 judgments with 9.9 to indicate complete dominance of one item over another.

However, based on the results of the focus groups, we found that it is necessary to allow the patient to clearly discriminate between alternatives that are close and somewhat indistinguishable. For this reason, we allow the use of judgments of 1.3, 1.5, 1.7, and 1.9. For example, a judgment of 1.5 indicates that, for items that are close and somewhat indistinguishable, one item is strongly (i.e., 50%) more important than the other. Therefore, to make the scale as simple as possible without sacrificing meaningful choices, the truncated AHP scale used for this study is: 1, 1.3, 1.5, 1.7, 1.9, and 9.9. As part of the decision-counseling protocol, appropriately sized bars, as well as words, are used to illustrate these differences in strength of preference.

- (3) Minimizing the need to review and revise the patient's pairwise comparisons.

During the standard AHP, several revision cycles are possible, especially if some sets of judgments are inconsistent. Given the desire to control the time required for, and the patient's interest in, the decision phase, revision cycles should be eliminated if possible.

Using the truncated AHP scale mentioned in point 2 minimizes the number of inconsistent cases that can result. Specifically, since there are six possible pairwise comparison values and three required pairwise comparisons for the criteria (most important compared to second, second to third, and most important to third), we have $6 \times 6 \times 6 = 216$ distinct sets of judgments. For each of the 216 cases, we computed the inconsistency ratio and found that only six of these exceed the generally

accepted level of 0.10 [36]. Therefore, in our study, judgment revision cycles were substantially limited.

(4) Use appropriate language to express strength of preference and the results of the decision process.

After extensive discussion, the words used to describe the truncated AHP scale preferences and the results of the AHP analysis were modified as follows:

Judgment	Verbal description
1	About the same importance
1.3	A little bit more important
1.5	Somewhat more important
1.7	A lot more important
1.9	A whole lot more important
9.9	Overwhelmingly important

Based on these modifications and simplifications, a counseling protocol was designed for use by a trained health educator. Steps involved in the protocol are summarized below:

1. The health educator meets the patient, reviews the informational booklet, and responds to questions related to its content. Responses are recorded on a hard copy form.
2. The health educator prompts the patient to identify criteria by asking him to complete the following sentences, "*I want to have a prostate screening examination because . . .*" and "*I don't want to have a prostate cancer screening examination because . . .*" For each sentence, the patient is encouraged to provide up to three responses. All responses are recorded on a hard copy form.
3. The patient is asked to identify and rank (first, second, third) the three most important responses given in point 2 above. These responses are the criteria used in the process. The rankings of the criteria are recorded on a hard copy form.
4. With respect to the most important criterion, the patient indicates whether this criterion leads him toward having the exam or not having the exam (to establish the direction of preference). Next, the patient indicates the strength of preference of the selected option (having or not having the exam) using the truncated AHP scale. This process is repeated for the second most and third most important criteria and recorded on a hard copy form.
5. The patient is guided through a process of pairwise comparisons of the three criteria (i.e., first to second, second to third, and first to third). The truncated AHP scale is used to capture these judgments. The responses are recorded on a hard copy form.
6. The health educator enters all of the judgments from steps 4 and 5 into a programmable hand-held calculator that executes an algorithm to compute the final priorities of the decision alternatives. The alternative with the highest priority is identified, and this priority is called the decision preference score. The health educator validates the score with the patient.
7. The results are transferred to a hard copy form that displays the patient's preferred option and score, a bar graph that represents the strength of preference for the exam and no exam alternatives (using the truncated AHP-based scale as mentioned above), and explanatory text.

The decision preference score reflects the strength and direction of the individual's preference in favor of one decision alternative (e.g., have a screening exam) as compared to another alternative (e.g., not have a screening exam). As will be shown in the discussion of the results, the decision preference score may indicate that the alternatives are equally preferred or it may signal the degree to which one alternative is preferred over the other.

5. Testing the decision-counseling protocol in primary care settings

The decision-counseling protocol was tested in four primary care practices in Philadelphia. We report preliminary findings from one of those settings, a large university-based practice. A total of 329 men were identified who were 50–69 years of age; had no history of prostate cancer, prostate ultrasound or biopsy, or benign prostatic hyperplasia (enlargement of the prostate); had been seen at the practice in the past 2 years; had a current address in the Philadelphia area; and for whom race/ethnicity was indicated in the database. Each man was mailed an advance letter that described the study and indicated that he would be contacted to complete a baseline telephone survey. We completed a baseline telephone survey for 103 men. We sent a mailed version of the survey instrument to non-respondents and received completed surveys from an additional 96 men. Thus, a total of 199 (63%) men completed a baseline survey.

Upon completion of the baseline survey, men were randomly assigned to either a control group ($N = 99$) or an intervention group ($N = 100$). The men in the control group received a mailed copy of the informational booklet. The men in the intervention group were mailed a copy of the booklet and received a telephone call to arrange an office visit with a health educator for a face-to-face informational session on prostate cancer screening. We completed a decision-counseling session with 60 men in the intervention group. Reasons for not completing the session included unavailable during study period ($N = 20$), refused ($N = 9$), no longer a patient in the practice ($N = 5$), serious illness ($N = 4$), and deceased ($N = 2$).

6. Characteristics of the patient population

Inspection of baseline survey data (199 men) showed that 70% of the men were 50–59 years old. Twenty-one percent of the men were African-American, 75% were white, 3% were Asian or Pacific Islanders, and 1% were Hispanic. Almost three-quarters of the men were married. Seventy percent had less than 12 years of education, 23% were high school graduates, and 7% had some post-secondary education. Nine percent of the men reported a family history of prostate cancer. Less than half (44%) had had both a DRE and PSA test in the previous year.

7. Results for the intervention group

As mentioned, men in the intervention group were asked to identify the three most important criteria that they thought were likely to influence whether or not to have a screening exam. Responses were recorded and assessed using content analysis techniques. The principle investigator and two

health educators from the research team reviewed the responses and independently established unique content categories. Using these categories, consensus was reached regarding a final set of criteria that relate to wanting or not wanting a screening examination. For example, criteria leading some men toward having a screening examination, called positive criteria, include:

- (1) perception of a positive effect on their current health,
- (2) perception of a positive effect on their long-term well-being,
- (3) encouragement by health care providers, and
- (4) encouragement by family members or friends.

For example, criteria leading some men toward not having a screening examination, called negative criteria, include:

- (1) perception of a negative effect on their current health,
- (2) perception of a negative effect on long-term well-being,
- (3) discouragement by health care providers,
- (4) discouragement by family members or friends,
- (5) feeling uncomfortable or embarrassed about having the test, and
- (6) belief that the test is inconvenient or expensive.

The 60 men in the intervention group could identify any combination of positive and negative criteria. We found that 40 men (67%) identified three positive criteria, while the remaining 20 men (33%) identified one or more negative criteria. The most frequently cited positive criterion was the one related to the perceived effect of screening on current health. Alternatively, the most frequently mentioned negative criterion was related to the perceived effect of screening on long-term well-being. For each of the men, AHP priorities for having and not having the examination were computed. Since these priorities sum to one, the results are expressed in terms of the AHP priority for having the examination, called the decision preference score. The resulting distribution of scores and associated decision preference and strength of preference are displayed in Table 1. Of the 60 respondents, only five did not have a preference toward having the examination. We note that the purpose of our study is not necessarily to increase the percentage of men taking the test, but to provide decision support to help men reach a decision that provides them with a high level of satisfaction.

The decision preference score ranges and their corresponding verbal descriptions directly relate to the modified AHP scale that was used to elicit judgments as described in the previous section. The research team believed that it was important to attribute verbal descriptions to the resulting weights in order to express strength as well as directionality of preference. The decision preference score ranges were developed as follows. A decision preference score of 0.500 corresponds to “no preference” about having or not having the examination, and so this value is set at the center of the “no preference” range. As previously discussed, a pairwise comparison of 1.3 corresponds to “a little bit more preferred.” Therefore, since a pairwise comparison of 1.3 in favor of having the examination over not having the examination results in a decision preference score of 0.565, this value was placed at the center of the “a little bit more preferred” range. Since we did not distinguish between a pairwise comparison of 1.1 and 1.0, we set the “equally preferred” range to encompass the range associated with the 1.1 comparison or a decision preference score of 0.524. Therefore, the

Table 1
Screening decision preference score, direction, and strength ($N = 60$)

Preference score	Direction and strength	Number	(%)
<i>Do not have an exam</i>			
0.000–0.332	Overwhelmingly preferred	1	(1.7)
0.333–0.356	Very much more preferred	0	
0.357–0.383	Much more preferred	2	(3.3)
0.384–0.416	Somewhat more preferred	0	
0.417–0.454	A little bit more preferred	0	
<i>Unsure about having an exam</i>			
0.455–0.544	No preference	2	(3.3)
<i>Have an exam</i>			
0.545–0.582	A little bit more preferred	3	(5.0)
0.583–0.615	Somewhat more preferred	2	(3.3)
0.616–0.643	Much more preferred	4	(6.7)
0.644–0.666	Very much more preferred	4	(6.7)
0.667–1.000	Overwhelmingly preferred	42	(70.0)

lower end of the range for “a little bit more preferred” is $0.565 - 0.500 \times (0.565 - 0.524)$ or 0.545, while the upper end is $0.565 + 0.500 \times (0.600 - 0.565)$ or 0.583. The other ranges are computed in a similar fashion. The only exception is the lower end for the “overwhelmingly preferred” range. This endpoint was set using the pairwise comparison of 2, which corresponds to a decision preference score of 0.667. Although a pairwise comparison of 2 was not used in this study, it was selected since it is the first pairwise comparison greater than 1.9 and therefore outside of the “very much more preferred” range.

Using the results in Table 1, we see that about 92% of the men had a decision preference score indicating that they preferred having the exam. Most of these scores indicated an overwhelming preference towards having the exam. Approximately 3% of the men had a score that indicated that they had no preference about having the exam; while 5% of the men had a score that indicated that they preferred to not have the exam.

We have moved forward on this investigation by administering an endpoint survey questionnaire and by conducting an endpoint chart audit. The questionnaire and chart audit were used to collect information for each study participant at a point that was at least 6 months after the prostate cancer informational booklet was provided. A total of 137 of 199 study participants (69%) completed the endpoint survey, providing measures for the control group and intervention group of cognitive, affective, social influence, and intention factors related to prostate cancer screening. We also assessed whether or not the respondent discussed prostate cancer screening with his primary care physician subsequent to informational booklet mailing. By comparing these measures for the two study groups, we will be able to ascertain long-term intervention effects.

Endpoint chart audits were completed for all 199 men who were enrolled in the study. Data collected via this chart audit will be used to determine if there were differences between the study groups relative to prostate cancer screening behavior. These analyses are currently underway.

8. Conclusions

In this study, a multidisciplinary research team developed and implemented a decision-counseling protocol based on the AHP. Of the 100 men asked to participate in this study, 60 completed the process. Further refinement of the methods used may lead to higher levels of participation. Also, increased participation might occur if the protocol were linked to a patient's appointment at the physician's office.

While health educators involved in the study required some training, none was needed for the patients. It is important to note that regardless of educational or social background, the patients were capable of identifying the criteria and making the necessary judgments. This finding supports the notion that AHP offers a natural means for eliciting preferences.

The results of this study have demonstrated that a well-designed decision-counseling protocol administered by a trained facilitator can be successfully implemented in a primary care patient population. Future research should focus on refining decision-counseling methods and on testing this type of decision aid in other areas of medical decision making (e.g., utilization of screening tests for other chronic diseases, selection of treatment options, participation in clinical trials). Equally as important, this study also offers the promise of expanding the application of the AHP into new personal decision-making areas.

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Matthew J. Liberatore, Ph.D., is the John F. Connelly Chair in Management and Professor of Decision and Information Technologies at Villanova University. Dr. Liberatore has published over 50 journal articles in management science, information systems, project management, and R&D management, and has led or participated in grants funded by organizations such as the National Science Foundation and the National Institutes of Health. His current research focuses on project selection and scheduling and medical decision making.

Dr. Ronald E. Myers is Professor of Medicine, Department of Medicine, Division of Genetic and Preventive Medicine, Jefferson Medical College, Thomas Jefferson University. He has been principal investigator on a number of National Institutes of Health-funded research grants and has numerous peer-reviewed publications in the field. His areas of expertise include patient adherence to cancer screening, physician follow-up of abnormal cancer screening test results, informed decision making in cancer susceptibility testing and clinical trials participation.

Robert Nydick, Ph.D., is Associate Professor and Chair of the Department of Decision and Information Technologies at Villanova University. Dr. Nydick has published numerous articles in the decision support and education of management science areas and has participated in grants funded by the National Institutes of Health, the Department of Defense, and Aetna U.S. Healthcare. Most recently his research has focused on the application of the analytic hierarchy process in medical decision making settings.

Dr. Michael Steinberg is assistant professor in the Department of Medicine, Division of General Internal Medicine at UMDNJ-Robert Wood Johnson Medical School with a dual appointment at the UMDNJ-School of Public Health. His clinical and research interests include clinical preventive services and tobacco dependence treatment in primary care and hospital settings. He has published and presented on several topics related to preventive medicine and tobacco issues.

Earl R. Brown, M.D., Roy Gay, M.D., Thomas Powell, M.D., and Roberta Lee Powell, M.D. are physicians engaged in primary care practices in Philadelphia, PA.

Behaviors Used by Men to Protect Themselves Against Prostate Cancer

Elisabeth J.S. Kunkel, M.D. *

Birgit Meyer, M.D. *

Constantine Daskalakis, Sc.D. †

James Cocroft, M.A. §

Kathleen Jennings-Dozier, Ph.D. ‡

Ronald E. Myers, Ph.D. §

* Department of Psychiatry and Human Behavior, Thomas Jefferson University

† Biostatistics Section, Division of Clinical Pharmacology, Department of Medicine, Thomas
Jefferson University

‡ College of Nursing and Health Professions, Drexel University, Hahnemann Campus
(Deceased May 2002)

§ Behavioral Epidemiology Section, Division of Genetic and Preventive Medicine, Department
of Medicine, Thomas Jefferson University

Corresponding Author:

Elisabeth J.S. Kunkel, M.D.
Department of Psychiatry and Human Behavior
Consultation-Liaison Psychiatry
1020 Sansom Street
Thompson Building, Suite 1652
Philadelphia, PA 19107
Voice: 215-955-6685
Fax: 215-955-8473

Requests for reprints should be addressed to Dr. Kunkel.

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Abstract

Objective. This paper reports on behaviors men use to protect themselves against prostate cancer.

Methods. Data were collected via a telephone or mailed survey from 353 men enrolled in two studies of prostate cancer screening. Respondents reported behaviors they used to protect themselves against prostate cancer and responses were coded as conventional care, self-care, or nothing. Men who reported using both conventional care and self-care were categorized as conventional care users. Polytomous logistic regression was conducted to evaluate the association between sociodemographic background, prior prostate screening, and cognitive, affective, and social support and influence factors with protective behavior type.

Results. The distribution of protective behaviors was as follows: conventional care, 63%; self-care only, 19%; and nothing, 18%. In multivariable analyses, higher education level was found to be positively associated with conventional care use. Perceived salience and coherence of prostate cancer screening was positively associated with conventional care use among men in one of the two studies. Low concern about screening was positively associated with self-care use, as was mailed survey completion.

Conclusions. This study presents self-report data regarding prostate cancer protection behaviors. Most men in the study reported using some type of prostate cancer protective behavior. Decision making about whether or not to take protective action and what type of behavior to use may be influenced by socioeconomic background, cognitive perceptions related to behavioral options, and concern about risk.

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Introduction

In the United States, 220,900 new cases of prostate cancer and 28,900 deaths are estimated for 2003 (1). Prostate cancer is the second leading cause of cancer-related mortality in men.

Prostate cancer screening is controversial (2,3), as there is no epidemiologic evidence to support that prostate cancer screening with PSA will reduce mortality. Different professional societies have each suggested guidelines for screening that vary considerably. The United States Preventive Services Task Force (USPSTF) (2002), states that there is insufficient evidence to recommend for or against routine prostate cancer screening with PSA or DRE, as the potential benefits are unclear and the potential for harm as a result of screening is evident (4,5). The American Cancer Society (ACS) (2001) recommends that prostate specific antigen (PSA) and digital rectal examination (DRE) be offered annually to men 50 years or older who are expected to live at least 10 years (6). Both the ACS and the American Urological Association (AUA) support the premise that men who ask their clinicians to decide about prostate cancer screening should be tested (6,7). The American College of Physicians (ACP) recommends that after weighing the risks and benefits of screening, an individualized decision should be made with the patient (8). All of the above organizations support informed decision-making about prostate cancer screening.

Despite reservations about the usefulness of screening, physicians commonly use DRE and PSA testing to detect early prostate cancer. Estimates from the Behavioral Risk Factor Surveillance System (2001) indicate that 57% of men 50 or more years of age have had a PSA test within the past year, and 56% of men have had a DRE within the past year (9). The use of PSA is comparable among white nonhispanic males and African American nonhispanic males, but the use of DRE is lower in African American nonhispanic males (10). Reports in the literature on screening test use provide little insight into what men are doing that they believe

protects them from developing this disease. Indeed, being screened for prostate cancer is just one possibility. Other methods include, but are not limited to, getting regular exercise, eating a healthy diet, and taking vitamins/nutritional supplements.

Recent reports have drawn attention to the potential that chemoprevention, vitamin supplements, and dietary modification hold relative to prostate cancer prevention (2, 11-17). In one report, it was suggested that a low-fat, high-fiber diet may protect against prostate cancer (18). It has also been reported that consumption of isoflavones, found in many soy products, may help to prevent prostate cancer (19). Another investigation showed that there was a positive association between vitamin supplement use and decreased prostate cancer-risk (20). Such reports, along with stories appearing in the lay media, are provocative and may serve to spur the use of a wider spectrum of protective behaviors against prostate cancer, either alone or in conjunction with conventional medical care.

The study reported here seeks to provide insight into the use of conventional care and other behaviors used for protection against prostate cancer. This report draws on data collected in two randomized controlled trials of a prostate cancer screening decision-counseling intervention. Specific aims of both trials were to: (1) assess the impact of a decision counseling intervention on prostate cancer screening utilization, (2) identify factors associated with screening utilization, and (3) assess the intervention impact on participant knowledge, attitudes, and beliefs related to prostate cancer and screening. In this paper, we report on our findings regarding factors associated with self-reported protective behaviors, as reported on the baseline survey obtained from the participants in the two trials.

Methods

Study design and study population

This investigation involved men who participated in two parallel, IRB-approved, randomized trials designed to evaluate a behavioral intervention intended to facilitate informed decision-making about prostate cancer screening. Participants in the first trial (Study 1) were patients of three community-based primary care practices, while those in the second trial (Study 2) were patients enrolled in a university-based primary care practice (Jefferson Internal Medicine Associates, JIMA). Both studies were conducted in Philadelphia, PA. Study 1 included only African American men between 40 and 69 years of age, while Study 2 included both white and nonwhite men aged 50 to 69. For both trials, eligibility was limited to patients who had visited their respective primary care practices in the previous two years and who had no personal history of prostate cancer, benign prostate hyperplasia, prostate biopsy, or transrectal ultrasound. The trials were otherwise similar in design, procedures, and data collection. Each participant completed a baseline survey, either by telephone (interview conducted by Mathematical Policy Research, Inc., Princeton, NJ) or by mail, before randomization.

Of 921 potentially eligible men, 520 were contacted and were eligible; 234 men were contacted but were ineligible; and 167 couldn't be contacted. Of 520 eligible men who were contacted, 441 (85%) completed a baseline survey (242 men in Study 1; 199 men in Study 2). The study sampling design and enrollment for the two trials is shown in Figure 1.

[Insert Figure 1 about here]

The study population for Study 1 was drawn from a sampling frame of 488 men. Initially, attempts were made to interview these men by telephone. Upon contact, 100 (20%) of these men were found to be ineligible, 205 (42%) completed the survey over the phone, and 43 (9%) refused. The remaining 140 (29%) men who could not be contacted by telephone were sent a

self-administered version of the baseline survey by mail. Of those, 27 men were found to be ineligible on the basis of their responses to the survey screener, 37 returned a completed survey, one refused to participate, and 75 did not respond. Thus, the final study sample was 242 (205+37).

The study population for Study 2 was drawn in two waves from an initial sampling frame of 433 men. We attempted to contact the first sample of 318 men by telephone. Upon contact, 63 (20%) men were found to be ineligible, 103 (32%) completed the baseline survey, and 35 (11%) refused. The remaining 117 (37%) men who could not be contacted by telephone, as well as a second wave of 115 men, were sent a mailed version of the survey. Of those, a total of 44 (21+23) were found to be ineligible, 96 (44+52) returned a completed survey, and 92 (50+42) did not respond. Thus, the resulting study sample consisted of 199 men (103+44+52).

Subsequent to survey completion, participants were randomized to one of two groups: an enhanced intervention group (receipt of a mailed informational booklet on prostate cancer screening and participation in a decision counseling session on prostate cancer screening mediated by a health educator) or a minimal intervention group (receipt of a mailed informational booklet only). This report is based only on baseline survey (pre-randomization) data; trial endpoint data are not reported here.

Study outcome and other measures

Baseline survey data were collected using an instrument that operationalized the Preventive Health Model (PHM) constructs. The PHM is an explanatory framework based on concepts from Antonovsky's work on the coherence of health behavior in everyday life (21), the Health Belief Model (22), theory of Reasoned Action (23), and Social Cognitive theory (24). The baseline survey instrument, which has been validated as a measure of knowledge, attitudes, and beliefs related to cancer early detection (25), allows for the collection of data on study factors, as

well as a subject's background characteristics, cognitive and psychological representations, social support and influence, and intention. The PHM previously has been useful in explaining cancer screening intention and adherence (26,27).

At the time of the baseline survey, study participants were asked if they had had a DRE or PSA in the past 12 months. They also were asked to respond on the telephone or mailed survey to the following question: *"What, if anything, are you doing to protect yourself from developing prostate cancer?"* For the telephone survey, this was an open-ended question; responses were recorded verbatim and were then categorized as screening; watching what I eat (reducing fat, increasing fiber); getting regular exercise; taking vitamins/supplements; other (specify); or nothing. On the mailed survey, recipients were presented a list of choices, including "Watching what I eat, like reducing the amount of fat or eating more fiber," "Getting regular exercise," "Taking vitamins and/or nutritional supplements," "Not doing anything in particular," and "Don't know." In addition, the men could write in other protective behaviors in a space provided ("Other"). Responses from both survey modes initially were classified as: 1) doing nothing, 2) engaging in self-care only, 3) undergoing conventional care, or 4) using both self-care practices and conventional care. Classifications of responses were performed by three of the co-investigators and discrepancies were resolved through discussion. All final determinations were unanimous. Categories then were combined to create three final categories: 1) doing nothing; 2) self-care only; and 3) conventional care alone or combined with self-care.

"Self care" was defined here as voluntary health behaviors (e.g., using diet, exercise, vitamins or supplements, taking medications, or other behaviors outside of a medical practice setting, used in order to reduce or eliminate personal risk for developing prostate cancer). Protective health behaviors (e.g., medication use) that are recommended or prescribed by health care professionals for purposes other than prostate cancer protection, but are perceived by

patients as protective were also placed under “self-care.” “Conventional care” included recommended procedures that health care professionals offer or perform (e.g., DRE, PSA testing, physical exams) in a medical practice setting. The definitions of self-care and conventional behaviors were intended to distinguish between behaviors strictly tied to conventional medical recommendations (e.g., PSA testing or DRE) versus self-care behaviors that the participant might initiate, believing that such self-care behaviors might prevent prostate cancer (irrespective of whether or not such behaviors are scientifically shown to be protective).

Sociodemographic background characteristics included the participant’s race (white vs. nonwhite), age (40-49, 50-59, 60-69 years), place of birth (Philadelphia vs. other), level of formal education (12 years or less vs. more than 12 years), marital status (married vs. not married), and history of prostate cancer in father or brothers (yes/no). Factors related to prostate cancer early detection were ascertained using a number of PHM-based items, measured with a four-point Likert-type response pattern (i.e., 1 = strongly disagree, 2 = sort of disagree, 3 = sort of agree, and 4 = strongly agree). On the basis of exploratory factor analyses, four scales were constructed: salience and coherence of prostate cancer screening (8 items, Cronbach’s $\alpha = 0.76$); perceived susceptibility to prostate cancer (3 items, $\alpha = 0.64$); worry and concern related to prostate cancer screening (7 items, $\alpha = 0.64$); and intention to have prostate cancer screening (4 items, $\alpha = 0.89$). In addition to these four scales, five additional constructs were measured: self-efficacy (1 item), curability of prostate cancer (1 item), social support (2 items), social influence (2 items), and knowledge about prostate cancer (1 item) (see Appendix).

A scale score was computed by averaging the scale’s items only when more than half of those items had no missing values. Some items were reverse-coded before averaging, so that higher scale scores were expected to correlate with more frequent screening (e.g., all “worry and concern” items were reverse-coded, so that higher levels of concern corresponded to lower

scores). We considered categorizing or dichotomizing the scales and single items, but the choice of cutpoints was unclear. Because of the varying and often very skewed distributions, using *a priori* cut-points were not an attractive option, as they can typically yield very unbalanced categories (i.e., some with a large number of subjects and others with very few). On the other hand, we wanted to avoid defining cutpoints *a posteriori* in order to not inflate the false-positive rate of our findings. Therefore, we used all scales and single items as continuous variables (1 to 4). This approach has the disadvantage of assuming approximate linearity of effect. For example, if a variable's effect is U-shaped, this approach will not detect it. However, since the prior expectation was for a monotonic effect of these variables on protective behaviors, using the scales as continuous predictors amounts to a trend test and is reasonable in this context.

Statistical methods and analyses

After preliminary descriptive analyses, we modeled the protective behaviors as a function of covariates via polytomous logistic regression. Initial univariable analyses were followed by full multivariable modeling. Polytomous logistic regression is the generalization of logistic regression for the case of an outcome that has more than two categories. In analyses performed here, the protective behaviors outcome has three levels: 0 = nothing, 1 = self-care only, and 2 = conventional care (with or without self-care).

Data from both studies were pooled in a single analysis, but a study indicator was included as a covariate (0 = Study 1, 1 = Study 2). For each of the other independent variables, we allowed for the possibility that its association with protective behaviors might vary across the two studies, an important consideration since the two trials were conducted in different populations and settings and had different modes of baseline data collection. A simple model with a single such covariate (EDUCATION: 0 = ≤ 12 years, 1 = > 12 years) can be written as

$$\begin{cases} \text{logit } \frac{\pi_1}{\pi_0} = \beta_0^{(1)} + \beta_1^{(1)} \text{STUDY} + \beta_2^{(1)} \text{EDUC} + \beta_3^{(1)} (\text{STUDY} * \text{EDUC}) \\ \text{logit } \frac{\pi_2}{\pi_0} = \beta_0^{(2)} + \beta_1^{(2)} \text{STUDY} + \beta_2^{(2)} \text{EDUC} + \beta_3^{(2)} (\text{STUDY} * \text{EDUC}) \end{cases}$$

where π_0 is the probability that a man does nothing, π_1 is the probability that he engages in self-care behaviors only, and π_2 is the probability that he has conventional care with or without self-care. The regression coefficients have the usual interpretation as log odds ratios. However, the polytomous logistic regression for a 3-level outcome involves two such sets of odds ratios. Specifically, the first equation refers to the odds of engaging in self-care as opposed to doing nothing; $\exp[\beta_2^{(1)}]$ compares high- to low-education subjects in Study 1, while $\exp[\beta_2^{(1)} + \beta_3^{(1)}]$ compares high- to low-education subjects in Study 2. The second equation refers to the odds of having conventional care with or without self-care as opposed to doing nothing. The corresponding odds ratios for education are $\exp[\beta_2^{(2)}]$ and $\exp[\beta_2^{(2)} + \beta_3^{(2)}]$, for Study 1 and Study 2, respectively.

This pooled approach has several advantages over analyzing each study separately. First, it allowed us to conduct a formal test of whether a covariate's association with protective behaviors was similar across the two studies (by testing the study-by-covariate interaction terms, e.g., $\beta_3^{(1)}$ and $\beta_3^{(2)}$). Second, it allowed us to estimate a common covariate effect for both studies, if the study-by-covariate interaction was found to be non-significant. Finally, estimates obtained from the pooled analysis had higher precision than study-specific estimates since they were based on a larger sample size (i.e., data from both studies).

For multivariable modeling, we started with a rich model that included all main effects, as well as all study-by-covariate interactions that allowed each factor's effect on protective behaviors to be different across the two studies. This model essentially corresponds to fitting separate logistic regressions for each study. We then formally tested each interaction ($\alpha = 0.05$)

using a backward elimination strategy. If the interaction were significant ($p < 0.05$), we retained it and estimated separate effects. Otherwise, we eliminated it and estimated a single common effect with increased precision.

The terms for study and for the participants' sociodemographic characteristics were retained in the model irrespective of their statistical significance. All other main effects were included only if they were significant ($p < 0.05$). Model selection and testing (p -values) were based on the likelihood ratio test. Wald-type confidence intervals were constructed for the odds ratios. Analyses were conducted in SAS 6.12 (SAS Institute Inc.) and Stata 7 (StataCorp).

Results

Baseline surveys were completed by 242 men in Study 1 and by 199 men in Study 2. Of these 441 men, 353 (80%) had complete data on study covariates and outcomes: 197 men (81%) in Study 1 and 156 men (78%) in Study 2. Table 1 shows the distribution of protective behaviors, which differed across the two studies ($p < 0.001$). The behaviors were distributed about evenly among men in Study 1, but conventional care behaviors (with or without self-care) were more common in Study 2.

[Insert Table 1 about here]

Table 2 shows the characteristics of the men in each study. Men in the two studies differed significantly on education level, place of birth, and several cognitive, affective, and social factors, and on mode of baseline survey. It should be noted that, by design, Study 1 included men who were African American and who were 40 to 69 years old, while Study 2 included both white and nonwhite men who were 50 to 69 years old.

[Insert Table 2 about here]

Table 3 shows the results of univariable analyses of protective behaviors. A number of variables (i.e., study, age, race/ethnicity, education level, survey mode, and perceived salience and coherence of screening) were significantly associated with protective behavior type.

[Insert Table 3 about here]

Table 4 shows the results of multivariable polytomous logistic regression analyses. The association between salience and coherence and protective behaviors was different across the two studies ($p = 0.012$); therefore, study-specific effects were estimated. In Study 1 (community practices), salience and coherence was inversely but non-significantly associated with the use of both conventional care and self-care. In Study 2 (university-based practice setting), perceived salience and coherence of prostate cancer screening was positively and significantly associated with the use of conventional care (and, to a lesser extent, with the use of self-care).

The association between each of the other independent variables and protective behavior was similar across the two studies, and therefore pooled estimates are presented. Education was the only sociodemographic variable that was significantly associated with protective behaviors (global p -value = 0.002). The overall significance of education was mainly due to its strong positive association with conventional care (although it also had a weaker association with self care). There was also an overall marginally significant association between worry and concern about prostate cancer screening and type of reported behaviors ($p = 0.05$). This appeared to be primarily due to increased odds of using self-care among men with lower worry and concern (i.e., higher scores on this scale), while the odds of conventional care were mostly unchanged. Finally, the odds of reported self-care were more than four times higher among men who responded to the mailed survey as compared to men who completed a telephone survey, while the odds of conventional care did not differ significantly by survey mode.

[Insert Table 4 about here]

Discussion

It has been reported elsewhere that men with higher education (2, 28-30) and those who view screening as salient and coherent may be more likely to undergo prostate cancer screening, a form of conventional care (28, 29, 31, 32). Findings reported here are similar to these reports. Specifically, conventional care use, as compared to nothing, was more common among men with a higher educational level than those with less education. The likelihood of self-care use, as compared to nothing, was also somewhat higher among those with higher education, but to a lesser degree.

We found that stronger belief in the salience and coherence of screening was associated with substantially increased odds of conventional care, as opposed to doing nothing, in the university practice setting. This pattern was reversed in the community practice study, where perceived salience and coherence of screening was inversely but non-significantly associated with both self-care and conventional care behaviors. We have no explanation for this difference and one can only speculate that it may be linked to some unmeasured characteristics of the two study populations.

In other research studies, measures of worry or concern about prostate cancer screening have been used to determine whether this construct differentiates men who had a screening exam from those who did not (27, 33, 34). Findings reported in the literature have not been consistent. Our findings, which are based on a measure of worry and concern that addresses both cancer and cancer screening, indicate that men who were less worried and concerned were more likely to engage in self-care (but not conventional care), as compared to doing nothing.

Men who completed the baseline survey by mail were also more likely to report using self-care (and, to a much lesser degree, conventional care), as compared to doing nothing, to protect

themselves from prostate cancer. Participants who completed a mailed survey tended to be younger and more educated than those who completed a telephone survey. However, because age and education were controlled for in the multivariable model, the association between survey mode and protective behaviors can only reflect respondents' differences on some other (unmeasured) characteristic, lifestyle, or environmental factor.

Alternatively, this association could be artefactual. In the mailed survey, self-care behaviors were presented as explicit choices, while in the telephone survey, an open-ended question was posed and spontaneous responses were recorded. Thus, the higher levels of self-care responses among mailed survey respondents might be due to the more direct prompting regarding such practices. This was a weakness in our survey design and underlines the need for consistency of data collection practices across different study phases and for different participant subgroups.

The use of self care as a general health care strategy has been reported in between 40 and 50 percent of Americans who have used complementary alternative medicine (CAM) (35), frequently in conjunction with conventional medicine (36-41). To date, many CAM studies have included diet, exercise, and vitamins (i.e., self-care) in their definitions of CAM. One large population-based survey conducted in South Carolina (42) showed a 44 percent overall use of CAM, with a slightly higher, although not statistically significantly different, level of use among whites (55%) as compared to African Americans (46%). Elsewhere, men and women from five different African American communities reported using conventional care, exercise, diet, smoking cessation, alcohol use reduction, and lifestyle change to maintain personal health or to prevent cancer (43). Inspection of the data from the current study shows that over half of the men reported using self-care either alone or in combination with conventional care as a prostate cancer protective strategy. This finding, while not a primary focus of the paper, is important, as there are no reports in the literature related to self-care use by men to protect themselves against

prostate cancer. Research is needed to learn about the way white and nonwhite men understand and decide to use different prostate cancer protective strategies, and whether sociodemographic, cognitive, affective, or social support and influence factors can predict screening behaviors. Finally, the role of the physician in determining the use of prostate cancer protective strategies should also be the focus of future study.

The current study is unique in that men were asked to report on behaviors they use to protect themselves from prostate cancer. To our knowledge, this is the first report in the literature that categorizes self-reported prostate cancer protective behaviors. Most study participants reported that they were protecting themselves from prostate cancer by using conventional care with or without self-care, while the proportions of men who reported using self-care only or doing nothing to protect themselves from this disease were relatively smaller. One limitation of the study is that men may have answered the survey question about protective behaviors affirmatively if they engaged in self-care or conventional care as part of their general health maintenance, i.e., not specifically just to protect themselves against prostate cancer. Future study in the area could clarify the distinction between general health behaviors (e.g., regular exercising) and behaviors specifically aimed at protecting oneself against prostate cancer.

The generalizability of findings from this report may be limited by the fact that both studies were carried out in one city in the Northeastern United States and study participants represented patients from only four primary care practices. However, we note that these practices included both community and university-based practices and that the associations between different variables and protective behaviors were largely similar across settings. Nevertheless, patients from other geographic regions and in other types of practice settings may differ in relation to self-reported protective behaviors, as well as other characteristics. Practitioners in various settings may also differ in terms of educational messages imparted to patients related to prostate

cancer protective behavior, and as a result may influence patient perceptions and self-reports of protective behaviors. Such factors might also modify the effects of the variables reported in this study. Furthermore, the results of this report are based on information obtained from subjects who consented to participate in a behavioral research study. The distribution of protective behaviors among persons not inclined to take part in such studies may differ.

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Figure 1
Survey Data Collection in Study 1 and Study 2

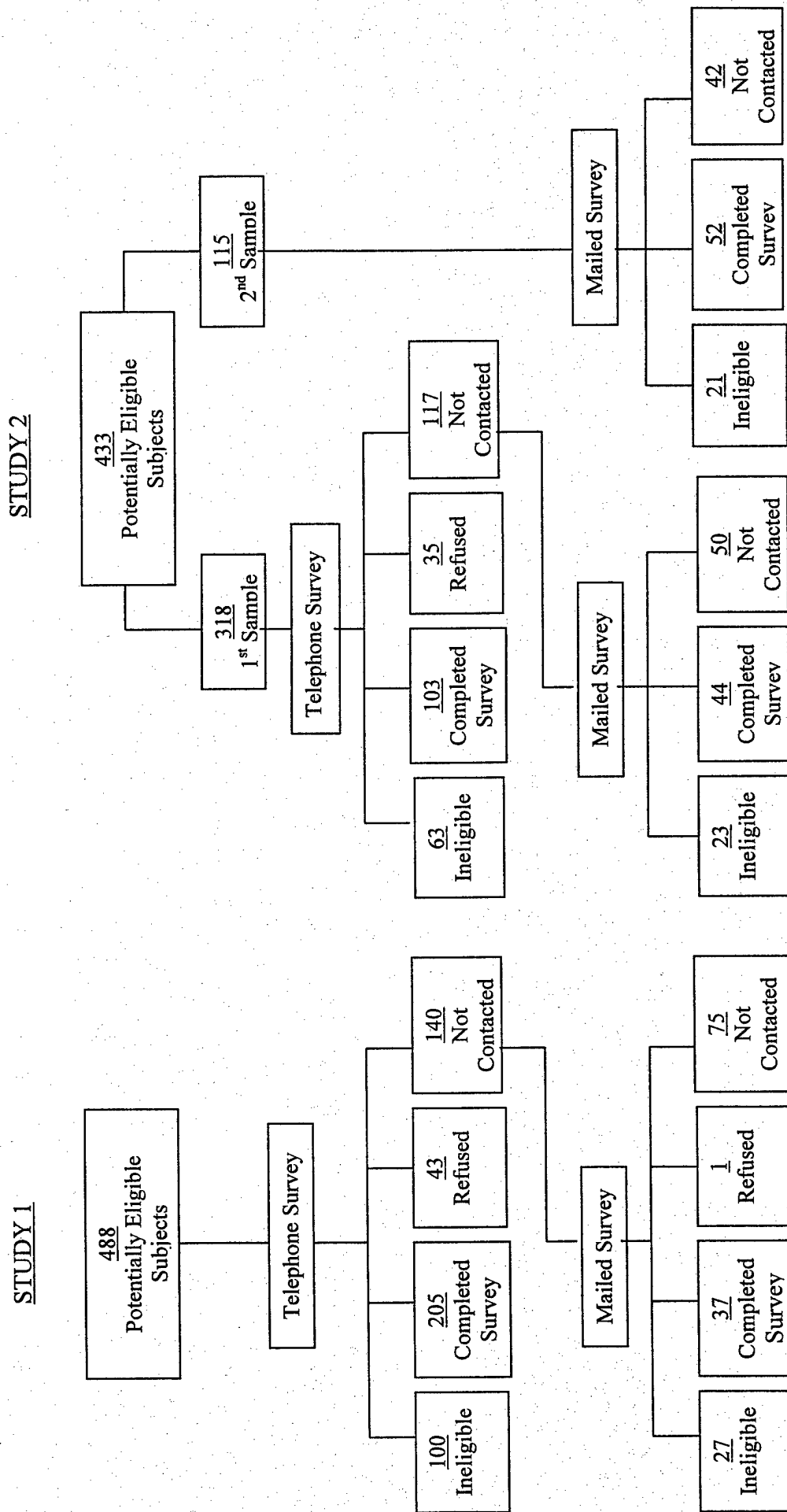


Table 1. Reported Prostate Cancer Protective Behaviors

	Study 1 ^a		Study 2 ^a		p-value ^b
	n	(%)	n	(%)	
Protective behaviors					<.001
Nothing	43	(22)	20	(13)	
Self-care only	49	(25)	19	(12)	
Conventional care ^c	52	(26)	51	(33)	
Conventional care with self-care ^c	53	(27)	66	(42)	
Total	197	(100)	156	(100)	

^a Study 1: 3 community-based primary care practices; Study 2: 1 university-based primary care practice.

^b P-value tests the difference between Study 1 and Study 2 with respect to protective behaviors.

^c Categories “conventional care” and “conventional care with self-care” were combined in subsequent analyses.

Table 2. Participant Characteristics

Variable	Study 1 ^a			Study 2 ^a			p ^c
	mean ± std	n	(%) ^b	mean ± std	n	(%) ^b	
Demographic characteristics							
Age (years)	52±7			57±5			
40 to 49		90	(46)		---	---	---
50 to 59		70	(36)		113	(72)	
60 to 69		37	(19)		43	(28)	
Race/ethnicity							---
Non-white		197	(100)		39	(25)	
White		---	---		117	(75)	
Education (in years) ^d							<.001
Less than 12		48	(24)		12	(8)	
12		71	(36)		38	(24)	
More than 12		78	(40)		106	(68)	
Marital status							0.107
Not married		70	(36)		42	(27)	
Married		127	(64)		114	(73)	
Place of birth ^e							<.001
Philadelphia		119	(60)		71	(46)	
Outside of Philadelphia, in US		65	(33)		77	(49)	
Outside of US		13	(7)		8	(5)	
Family history of prostate cancer							0.713
No		180	(91)		140	(90)	
Yes		17	(9)		16	(10)	
Baseline survey mode							<.001
Telephone		167	(85)		70	(45)	
Mail		30	(15)		86	(55)	
Cognitive, affective, and social factors							
Salience and coherence (8 items) ^f	3.7±0.5			3.7±0.3			
Worry and concern (7 items) ^f	3.2±0.5			3.4±0.5			<.001
Susceptibility (3 items) ^f	1.7±0.7			1.8±0.7			.034
Intention (4 items) ^f	3.4±0.8			3.1±0.9			.007
Self-efficacy ^f	3.3±1.0			3.6±0.7			.007
Curability ^f	3.7±0.6			3.7±0.6			.304
Social support from doctor ^f	3.3±1.0			3.7±0.7			<.001

Variable	Study 1 ^a			Study 2 ^a			p ^c
	mean ± std	n	(%) ^b	mean ± std	n	(%) ^b	
Social support from family ^f	3.3±1.0			3.4±0.9			.331
Social influence from doctor ^f	3.7±0.7			3.6±0.7			.436
Social influence from family ^f	2.9±1.2			2.7±1.2			.044
Knowledge ^f	2.8±1.1			3.3±0.8			.002

^a Study 1: 3 community-based primary care practices; Study 2: 1 university-based primary care practice.

^b Percentages may not add to 100 because of rounding.

^c P-values test the difference between Study 1 and Study 2 with respect to each variable. P-value is not reported for age or race/ethnicity because differences across the two studies are due to design.

^d Education was dichotomized as “less than or equal to 12” versus “more than 12” in the final analyses.

^e Place of birth was dichotomized as “Philadelphia” versus “Outside of Philadelphia” in the final analyses.

^f All items and scales used as continuous (scored from 1 to 4). Scoring for the Worry and Concern scale was reverse-coded. Thus, a higher scale score reflects lower worry and concern.

Table 3. Univariable Analyses of Protective Behaviors

Variable	Protective Behaviors						p-value ^c
	Nothing		Self-care ^a		Conventional care ^a		
	n	(%) ^b	n	(%) ^b	n	(%) ^b	
Study							<.001
Study 1	43	(22)	49	(25)	105	(53)	
Study 2	20	(13)	19	(12)	117	(75)	
Demographic characteristics							
Age (years)							.014
40 to 49	21	(23)	26	(29)	43	(48)	
50 to 59	27	(15)	30	(16)	126	(69)	
60 to 69	15	(19)	12	(15)	53	(66)	
Race/ethnicity							<.001
Non-white	48	(20)	57	(24)	131	(56)	
White	15	(13)	11	(9)	91	(78)	
Education (years)							<.001
Less than or equal to 12	42	(25)	37	(22)	90	(53)	
More than 12	21	(11)	31	(17)	132	(72)	
Marital status							.211
Not married	23	(21)	26	(23)	63	(56)	
Married	40	(17)	42	(17)	159	(66)	
Place of birth							.472
Philadelphia	37	(19)	39	(21)	114	(60)	
Outside of Philadelphia	26	(16)	29	(18)	108	(66)	
Family history of prostate cancer							.892
No	58	(18)	61	(19)	201	(63)	
Yes	5	(15)	7	(21)	21	(64)	
Baseline Survey Mode							.012
Telephone	51	(22)	39	(16)	147	(62)	
Mail	12	(10)	29	(25)	75	(65)	
Cognitive, affective, and social behaviors							
Salience and coherence ^d							.038
Worry and concern ^d							.457
Susceptibility ^d							.577
Intention ^d							.401

Variable	Protective Behaviors						
	Nothing		Self-care ^a		Conventional care ^a		p-value ^c
	n	(%) ^b	n	(%) ^b	n	(%) ^b	
Self-efficacy ^d							.382
Curability ^d							.637
Social support from doctor and family ^d							.282
Social influence from doctor and family ^d							.271
Knowledge ^d							.183

^a "Self-care" includes men with self-care only. "Conventional Care" includes men with conventional care with or without self-care.

^b Percentages indicate the proportion of each type of protective behavior at each level of a variable.

^c P-values test the difference of protective behaviors across levels of a variable.

^d All items and scales used as continuous (scored from 1 to 4). Scoring for the Worry and Concern scale was reverse-coded. Thus, a higher scale score reflects lower worry and concern.

Table 4. Multivariable analyses of Protective Behaviors

Variable	Protective behaviors				p-value ^c
	Self-care ^a vs. nothing		Conventional care ^a vs. nothing		
	OR ^b	95% CI ^b	OR ^b	95% CI ^b	
Study					.311
Study 1	1.00	Reference	1.00	Reference	
Study 2	0.40	0.06, 2.45	0.28	0.06, 1.41	
Age (years)					.373
40 to 49	1.06	0.41, 2.71	0.54	0.24, 1.19	
50 to 59	1.00	Reference	1.00	Reference	
60 to 69	0.94	0.36, 2.46	0.90	0.42, 1.91	
Race/ethnicity					.193
Non-white	1.00	Reference	1.00	Reference	
White	0.31	0.07, 1.33	0.80	0.24, 2.67	
Place of birth					.930
Philadelphia	1.00	Reference	1.00	Reference	
Outside of Philadelphia	1.11	0.53, 2.33	1.12	0.61, 2.07	
Education (years)					.002
Less than or equal to 12	1.00	Reference	1.00	Reference	
More than 12	1.47	0.66, 3.31	2.92	1.50, 5.70	
Marital status					.308
Not married	1.00	Reference	1.00	Reference	
Married	0.95	0.45, 2.01	1.44	0.76, 2.72	
Salience and coherence (1-point increase) ^d					.008
Study 1 ^e	0.43	0.14, 1.32	0.66	0.23, 1.88	
Study 2 ^e	1.27	0.25, 6.43	6.87	1.86, 25.5	
Worry and concern (1-point increase) ^d					.050
	1.93	0.92, 4.06	0.92	0.50, 1.68	
Baseline survey mode					.002
Telephone	1.00	Reference	1.00	Reference	
Mail	4.20	1.63, 10.83	1.31	0.58, 2.95	

^a "Self-care" includes men with self-care only. "Conventional Care" includes men with conventional care only and men with conventional care and self-care.

^b OR: odds ratio; CI: confidence interval.

- ^c P-values test the difference of protective behaviors across levels of a variable, adjusting for all other variables in the model (likelihood ratio test).
- ^d Scales used as continuous (scored from 1 to 4). Scoring for the Worry and Concern scale was reverse-coded. Thus, a higher scale score reflects lower worry and concern.
- ^e The association of Salience and Coherence with protective behaviors was significantly different across the two studies ($p = 0.012$).

Appendix: Survey Constructs, Scales, and Items

All items scored as: 1 = strongly disagree, 2 = sort of disagree, 3 = sort of agree, 4 = strongly agree

Multi-Item Scales

1. Salience and Coherence (8 items)

- a. Being treated for prostate cancer is likely to increase my chances of living a healthier life.
- b. I think the benefits of prostate screening outweigh any difficulty I might have in going through the tests.
- c. Being treated for prostate cancer is likely to increase my chances of living a longer life.
- d. Having a prostate screening test makes sense to me.
- e. I believe that going through prostate screening would help me to be healthy.
- f. Going through prostate screening is an important thing for me to do.
- g. I believe that prostate screening is an effective way to find prostate cancer early.
- i. I believe that I can protect myself from prostate cancer by going through screening.

2. Worry and Concern about Prostate Cancer and Screening (7 items; all reversed-coded)

- a. I am bothered by the possibility that prostate screening might be physically uncomfortable.
- b. I think prostate screening would be painful.
- c. If I have prostate cancer, I would just as soon not know about it.
- d. If I am meant to get prostate cancer, I will get it no matter what I do.
- e. Men who go through prostate screening will have more problems than men who do not go through screening.
- f. If I get prostate cancer, nothing can be done to cure me of the disease.
- g. Going through prostate screening would be embarrassing.

3. Prostate Cancer Susceptibility (3 items)

- a. I believe it is likely that I will get prostate cancer at some time in the future.

- b. I am afraid that if I have a prostate-screening test, the test result will show that I have prostate cancer.
- c. I think it is likely that I will develop prostate cancer.

4. Intention to Screen (4 items; items 4b and 4d reverse-coded)

- a. I intend to have a prostate screening examination in the next six months.
- b. I don't plan on having a prostate screening examination in the next six months.
- c. In the next six months, I intend to discuss prostate screening with a physician.
- d. In the next six months, I don't plan on talking to my doctor about prostate cancer.

Single-Item or Two-Item Constructs

5. Knowledge

I think that men who have a father or a brother with prostate cancer are more likely to develop prostate cancer than men who do not have a father or brother with prostate cancer.

6. Self-Efficacy

Arranging my schedule to go through prostate screening would be an easy thing for me to do.

7. Curability

I believe that when prostate cancer is found early, it can be cured.

8. Social Support

- a. The doctor I see is likely to think I should go through prostate cancer screening (with a rectal exam and a PSA blood test).
- b. Members of my immediate family are likely to think I should go through prostate screening.

9. Social Influence

- a. I want to do what the doctor I see thinks I should do about prostate screening.
- b. I want to do what members of my immediate family think I should do about prostate screening.

Is Being Checked for Prostate Cancer a Good or Bad Idea?

**You Have the Right to
Know the Facts
and Decide What to Do**



**Plain Talk for Men
Who Have Not
Had Prostate Cancer**



Introductory Letter

Dear Friend,

Most men will have prostate problems as they grow older. We feel that men should know about the prostate, problems that can develop with this gland, and what is involved in being checked for Prostate cancer.

This booklet provides information you can use to help decide whether you want to be checked for Prostate cancer. For some men, making this decision is easy. For other men, the decision is not so easy. It is important for all men to make this decision.

Please look through the booklet. Talk to a health care professional. Discuss the decision with your partner, other family members, and friends. Let us know if we can help.

Best regards.

Know That Opinions Vary

Some experts think it is a good idea to have a routine check-up for Prostate cancer. They say:

- "A check-up can find cancer early."
- "There may be a better chance for a cure."
- "Being checked can lower the chances that men will die from Prostate cancer."

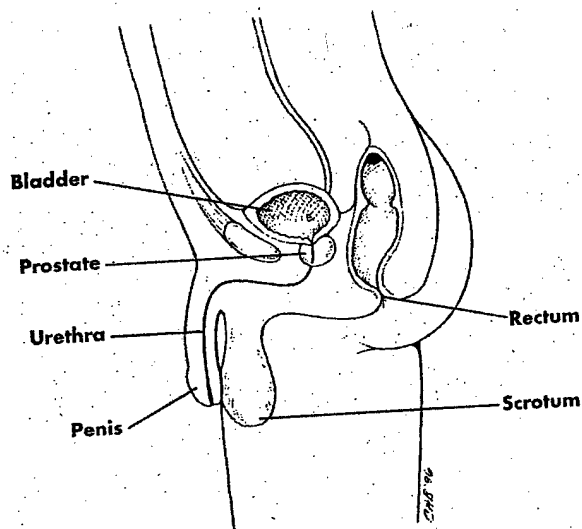
Other experts think it may not be a good idea to have a routine check-up for Prostate cancer. They say:

- "There is not enough proof yet that being checked will lower a man's chances of dying from Prostate cancer."
- "So far there is no way to tell the difference between a fast growing and a slow growing Prostate cancer. One may need treatment; the other may not."
- "Men may be harmed by tests and treatments they may not need."

This difference of opinion may make it hard to decide what to do. Information on the following pages can help you make up your mind.

Find Out About the Prostate

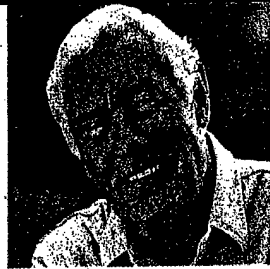
The prostate is a sex gland. It makes semen, the fluid that carries sperm. It is about the size of a walnut and is located in front of the rectum.



The prostate gland is shaped like a doughnut. The tube (urethra) that carries urine passes through it.

Know Who Is At Risk for Prostate Cancer

- **Men over age 50**



- **African American men over age 40**



Researchers are trying to find out why they are at risk at a younger age.

- **Men who have blood relatives who have had Prostate cancer**

For example, a father, grandfather, or brother.

A man can still develop Prostate cancer even if he doesn't fit into any of these groups.

Know the Signs of Prostate Problems

- Getting up often at night to pass urine
- Difficulty passing urine
- Pain or burning when passing urine
- Pain in the upper legs or lower back
- Blood in the urine.

Sometimes, these signs indicate problems that are not cancer. Sometimes, these signs indicate Prostate cancer. Men can have Prostate cancer without having any signs.

Prostate Problems

Problems that are not cancer:

- Enlarged or Swollen Prostate

This alone is not cancer.

- Infected or Inflamed Prostate

This alone is not cancer.

Prostate cancer:

- Cells begin to grow too fast
- Cell growth is uncontrolled
- There may be no symptoms
- Cancer can be life threatening

Find Out What is Involved in Checking for Prostate Cancer

Step 1: Having a Check-up

If you do decide to get checked, the first step involves a rectal exam and a blood test.

Rectal Exam

Using a gloved finger, the doctor can feel if the gland is hard or has lumps.

Blood Test

A medical lab will test a sample of your blood for something called PSA. (PSA is made by the prostate).



Talk to your doctor about what your test results mean for you. Sometimes, a test may give a false result.

Step 2: Having Follow-up Tests

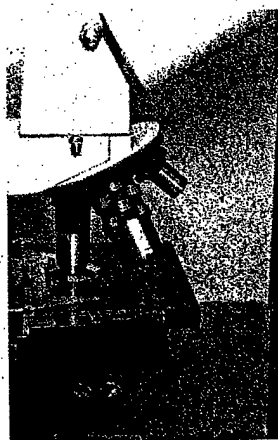
The second step is only for men who have abnormal check-up results. This involves an ultrasound and a biopsy.

Ultrasound

A small probe is placed in the rectum. This test uses sound waves to look at the prostate.

Biopsy

Very small pieces of tissue are removed from the prostate and looked at under the microscope.



**Most men will find they do not have cancer.
Some will have early stage Prostate cancer.
Some will have late stage Prostate cancer.**

Find Out What Can Be Done to Treat Prostate Cancer

Treating Early Prostate Cancer

Watchful Waiting

No surgery or radiation is used. The doctor continues to check on the cancer.

Surgery

The prostate gland and some tissue around it are removed.

Radiation

X-Rays are used to kill cancer cells. Or, very small radioactive pellets (seeds) are put directly into the prostate to kill the cancer cells.

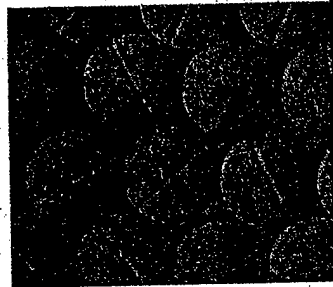
Treatment May Help and It Can Cause Problems

Treatment may give some men a chance for a cure. It can also cause a man to have problems holding his urine (incontinence), and having an erection (impotence).

Treating Late Prostate cancer

Medication

Medicine can be used to stop the body from making the hormones that the cancer needs in order to grow.



Surgery

The testicles can be removed to stop the body from making the hormone that the cancer needs in order to grow.

Chemotherapy

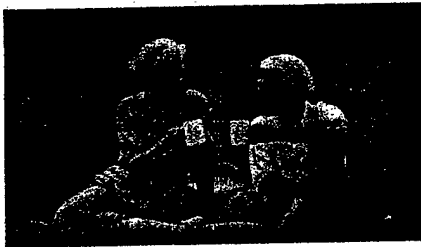
This treatment uses drugs that can kill cancer cells.

Treatment May Make a Difference

Late Prostate cancer is hard to cure. But, treatment may offer a man a chance to improve the quality and the length of his life.

Make Your Own Decision About Getting Checked

- **Think about the information in this booklet.**
- **Ask a health care professional that you trust to answer any questions you have.**
- **Discuss your decision with someone who is close to you.**



Your Opinion is Important

- **Deciding about whether or not to have a Prostate cancer check-up is an important thing to do.**



- **The more you know, the better decision you will make.**

- **You should feel satisfied with whatever decision you make.**

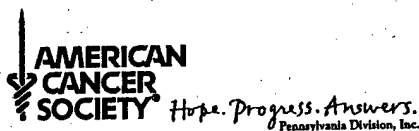
Notes



Kimmel Cancer Center
Thomas Jefferson University
NCI-designated

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and the Korman Foundation.



1-800-ACS-2343

www.cancer.org

**For some men,
the decision is easy...**

**...for other men,
the decision is
not so easy.**

ID#

First name

Last Name

month / day / year

Reasons for Being Tested and for Not Being Tested for Early Prostate Cancer Version 1, 7-20-00
(Circle all that apply and/or have been mentioned)

A. I want to be tested, because . . .

1. Testing can find the cause of a current health problem, and treatment is likely to be effective.
2. Testing can find a problem that could affect the quality of my life, and treatment is likely to be effective.
3. Testing can find a problem that could affect how long I will live, and treatment is likely to be effective.
4. Testing will let me know if I have a health problem, and I want to know.
5. I am worried about whether or not I have a health problem and testing will let me know if I should worry.
6. Someone important (doctor, family member(s), friend(s), other) recommends that I be tested and I want to follow that advice.
7. Other: _____

(Write in Response)

B. I do NOT want to be tested, because . . .

1. Testing can find the cause of a current problem but treatment is NOT likely to be effective.
2. Testing could find a problem that could affect my life but treatment is NOT likely to be effective.
3. Testing could find a problem that could affect my life but testing may lead to additional tests/treatment that can cause problems (e.g., incontinence, impotence, complications).
4. Testing may show that there is a problem that really isn't there (false positive) and lead to having unnecessary additional tests/treatment.
5. Testing may miss a problem that really is there (false negative) and lead to NOT having necessary additional tests/treatment.
6. Testing is likely to be painful and I don't want to feel pain.
7. Testing is likely to be embarrassing and I don't want to feel embarrassed.
8. I don't want to spend the time and effort involved in being tested.
9. I don't want to know if I have a prostate problem.
10. I am not worried about whether or not I have a prostate problem.
11. I don't trust health care professionals.
12. Someone important (doctor, family member(s), friend(s), other) recommends that I NOT be tested and I want to follow that advice.
13. Other: _____

(Write in Response)

C. Identify top 3 reasons in order of importance by writing in section letter and statement number.

Most important _____

Second most important _____

Third most important _____

Preference and Decision Related to Prostate Cancer Early Detection

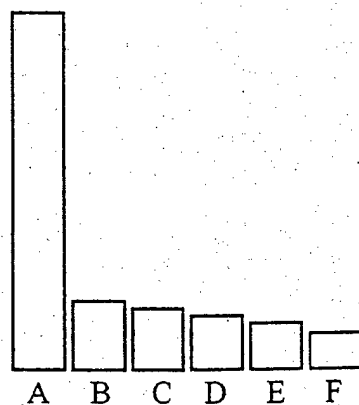
We have discussed making a decision about whether or not to have a prostate cancer early detection exam (rectal exam and PSA test). Your preferences and decision are summarized below.

1. Preference

A. Direction of preference indicated in session

- ☐ Have the exam. (Exam)
- ☐ Not have the exam. (No Exam)
- ☐ No preference.

B. Strength of preference indicated in session



- (A) Overwhelmingly preferred
- (B) Very much more preferred
- (C) Much more preferred
- (D) Somewhat more preferred
- (E) A little more preferred
- (F) About the same

Exam / No Exam
(Circle preference)

Exam / No Exam
(Circle alternative preference)

Comments

2. Decision at this time

- ☐ I want to schedule an exam.
- ☐ I do not want to schedule an exam.
- ☐ I am not sure about scheduling an exam.
- ☐ I want to talk to the doctor about the exam.
- ☐ Other _____

Participant:

Name _____

Signature _____

Interviewer:

Initials _____

Date _____

Survey on What You Think About Prostate Cancer Screening

Practice Name

&

Thomas Jefferson University

Inside Front Cover

To _____

About the Survey

The purpose of this survey is to learn what you think about screening for prostate cancer. It will take about 15 to 20 minutes to complete. All of your answers are confidential. Your name will not be used in any reports about this survey. Your responses will help us develop a special educational program for men in our practice.

How to Complete the Survey

For almost all of the items in this survey, please check only one response. If you are not sure, please check the response that is closest to your ideas. For Question A-5, please check all the responses that apply to you.

How to Return the Survey

Please return the survey in the envelope that comes with the survey. The envelope is addressed to Dr. Ronald E. Myers at Thomas Jefferson University. It already has postage stamps. You can just drop it into a mailbox.

After the Survey

After you complete the survey, we will give you some information about prostate cancer early detection. In about six months, we will ask you to complete a second survey. We also will review your medical record.

Part A. Screening for Prostate Cancer

This part has some questions about your experience with screening for prostate cancer. Screening to test for prostate cancer includes a rectal exam and a prostate specific antigen (or PSA) test.

A-1 In the past 12 months, have you had a rectal exam as part of a prostate cancer screening examination? This is when a physician or urologist puts a finger in the rectum (rear end) to do an examination.

- ☐ Yes → → → → → → →
☐ No
☐ Don't know



When was the exam done?

____ 19 ____
month year

☐ Don't know

A-2 In the past 12 months, have you had a blood test called a prostate specific antigen or PSA test as part of a prostate cancer screening examination?

- ☐ Yes → → → → → → →
☐ No
☐ Don't know



When was the exam done?

____ 19 ____
month year

☐ Don't know

A-3 Did a doctor ever tell your father that he had prostate cancer?

- ☐ Yes
- ☐ No
- ☐ Don't know

A-4 Do you have any brothers who were ever told by a doctor that they have prostate cancer?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ I have no brothers.

A-5 What, if anything, are you doing to protect yourself from developing prostate cancer?

CHECK ALL THAT APPLY TO YOU.

- ☐ Watching what I eat, like reducing the amount of fat or eating more fiber
- ☐ Getting regular exercise
- ☐ Taking vitamins and/or nutritional supplements
- ☐ Other Write in ➡ _____

- ☐ Not doing anything in particular
- ☐ Don't know

Part B. Ideas about Prostate Cancer Screening

This part has some statements about prostate cancer screening.
For each item, please check the one response that best describes how much you agree or disagree with the statement.

- | | | |
|------------|---|--|
| B-1 | The doctor I see is likely to think I should go through prostate screening (with a rectal exam and PSA blood test). | <input type="checkbox"/> Strongly AGREE
<input type="checkbox"/> Sort of agree
<input type="checkbox"/> Sort of disagree
<input type="checkbox"/> Strongly DISAGREE |
| B-2 | I believe it is likely that I will get prostate cancer at some time in the future. | <input type="checkbox"/> Strongly AGREE
<input type="checkbox"/> Sort of agree
<input type="checkbox"/> Sort of disagree
<input type="checkbox"/> Strongly DISAGREE |
| B-3 | Being treated for prostate cancer is likely to increase my chances of living a healthier life. | <input type="checkbox"/> Strongly AGREE
<input type="checkbox"/> Sort of agree
<input type="checkbox"/> Sort of disagree
<input type="checkbox"/> Strongly DISAGREE |
| B-4 | Arranging my schedule to go through prostate screening would be an easy thing for me to do. | <input type="checkbox"/> Strongly AGREE
<input type="checkbox"/> Sort of agree
<input type="checkbox"/> Sort of disagree
<input type="checkbox"/> Strongly DISAGREE |

- B-5** I am bothered by the possibility that prostate screening might be physically uncomfortable.
- ☐ Strongly AGREE
☐ Sort of agree
☐ Sort of disagree
☐ Strongly DISAGREE
- B-6** I intend to have a prostate screening exam in the next six months.
- ☐ Strongly AGREE
☐ Sort of agree
☐ Sort of disagree
☐ Strongly DISAGREE
- B-7** I think the benefits of prostate screening outweigh any difficulty I might have in going through the tests.
- ☐ Strongly AGREE
☐ Sort of agree
☐ Sort of disagree
☐ Strongly DISAGREE
- B-8** I have more important things to do than go for prostate screening.
- ☐ Strongly AGREE
☐ Sort of agree
☐ Sort of disagree
☐ Strongly DISAGREE
- B-9** I want to do what members of my immediate family think I should do about prostate screening.
- ☐ Strongly AGREE
☐ Sort of agree
☐ Sort of disagree
☐ Strongly DISAGREE
- B-10** I think prostate screening would be painful.
- ☐ Strongly AGREE
☐ Sort of agree
☐ Sort of disagree
☐ Strongly DISAGREE

B-11 If I have prostate cancer, I would just as soon *not* know about it.

- ☐ Strongly AGREE
- ☐ Sort of agree
- ☐ Sort of disagree
- ☐ Strongly DISAGREE

B-12 If I am meant to get prostate cancer, I will get it not matter what I do.

- ☐ Strongly AGREE
- ☐ Sort of agree
- ☐ Sort of disagree
- ☐ Strongly DISAGREE

B-13 Being treated for prostate cancer is likely to increase my chances of living a longer life.

- ☐ Strongly AGREE
- ☐ Sort of agree
- ☐ Sort of disagree
- ☐ Strongly DISAGREE

B-14 Having a prostate screening test makes sense to me.

- ☐ Strongly AGREE
- ☐ Sort of agree
- ☐ Sort of disagree
- ☐ Strongly DISAGREE

B-15 I believe that going through prostate screening would help me to be healthy.

- ☐ Strongly AGREE
- ☐ Sort of agree
- ☐ Sort of disagree
- ☐ Strongly DISAGREE

B-16 I do not plan to have a prostate screening exam in the next six months.

- ☐ Strongly AGREE
- ☐ Sort of agree
- ☐ Sort of disagree
- ☐ Strongly DISAGREE

- B-17** Men who go through prostate screening will have more problems than men who do *not* go through screening.
- ☐ Strongly AGREE
☐ Sort of agree
☐ Sort of disagree
☐ Strongly DISAGREE
- B-18** Going through prostate screening is an important thing for me to do.
- ☐ Strongly AGREE
☐ Sort of agree
☐ Sort of disagree
☐ Strongly DISAGREE
- B-19** I want to do what the doctor I see thinks I should do about prostate screening.
- ☐ Strongly AGREE
☐ Sort of agree
☐ Sort of disagree
☐ Strongly DISAGREE
- B-20** If I get prostate cancer, nothing can be done to cure me of the disease.
- ☐ Strongly AGREE
☐ Sort of agree
☐ Sort of disagree
☐ Strongly DISAGREE
- B-21** I think African American men are more likely to develop prostate cancer than white men.
- ☐ Strongly AGREE
☐ Sort of agree
☐ Sort of disagree
☐ Strongly DISAGREE
- B-22** I am afraid that if I have a prostate-screening test, the test result will show that I have prostate cancer.
- ☐ Strongly AGREE
☐ Sort of agree
☐ Sort of disagree
☐ Strongly DISAGREE

- B-23** Going through prostate screening would be embarrassing.
- ☐ Strongly AGREE
☐ Sort of agree
☐ Sort of disagree
☐ Strongly DISAGREE
- B-24** I think it is likely that I will develop prostate cancer.
- ☐ Strongly AGREE
☐ Sort of agree
☐ Sort of disagree
☐ Strongly DISAGREE
- B-25** I believe that prostate screening is an effective way to find prostate cancer early.
- ☐ Strongly AGREE
☐ Sort of agree
☐ Sort of disagree
☐ Strongly DISAGREE
- B-26** In the next six months, I intend to discuss prostate screening with a physician.
- ☐ Strongly AGREE
☐ Sort of agree
☐ Sort of disagree
☐ Strongly DISAGREE
- B-27** Members of my immediate family are likely to think I should go through prostate screening.
- ☐ Strongly AGREE
☐ Sort of agree
☐ Sort of disagree
☐ Strongly DISAGREE
- B-28** Because I do *not* have any prostate problems, it is *not* necessary for me to be tested for prostate cancer.
- ☐ Strongly AGREE
☐ Sort of agree
☐ Sort of disagree
☐ Strongly DISAGREE

- B-29** I believe that when prostate cancer is found early, it can be cured.
- ☐ Strongly AGREE
 - ☐ Sort of agree
 - ☐ Sort of disagree
 - ☐ Strongly DISAGREE
- B-30** I believe that I can protect myself from prostate cancer by going through screening.
- ☐ Strongly AGREE
 - ☐ Sort of agree
 - ☐ Sort of disagree
 - ☐ Strongly DISAGREE
- B-31** I think that men who have a father or brother with prostate cancer are more likely to develop prostate cancer than men who do *not* have a father or brother with prostate cancer.
- ☐ Strongly AGREE
 - ☐ Sort of agree
 - ☐ Sort of disagree
 - ☐ Strongly DISAGREE
- B-32** In the next six months, I do *not* plan on talking to my doctor about prostate cancer.
- ☐ Strongly AGREE
 - ☐ Sort of agree
 - ☐ Sort of disagree
 - ☐ Strongly DISAGREE

Part C. Interests and Concerns about Prostate Cancer Screening

This part has some statements about possible interests or concerns you might have about prostate cancer screening. For each item, please check whether you agree or disagree with each statement.

- | | | |
|------------|---|---|
| C-1 | I am interested in knowing if I have prostate cancer. | <input type="checkbox"/> Agree
<input type="checkbox"/> Disagree |
| C-2 | I am concerned about the cost of having a prostate cancer screening exam. | <input type="checkbox"/> Agree
<input type="checkbox"/> Disagree |
| C-3 | I am interested in having a prostate cancer screening exam only if I am certain that the results will be good for me. | <input type="checkbox"/> Agree
<input type="checkbox"/> Disagree |
| C-4 | I am concerned about the physical discomfort of having a prostate cancer screening exam. | <input type="checkbox"/> Agree
<input type="checkbox"/> Disagree |
| C-5 | I am interested in protecting my health. | <input type="checkbox"/> Agree
<input type="checkbox"/> Disagree |
| C-6 | I am concerned about finding the time to have a prostate cancer screening exam. | <input type="checkbox"/> Agree
<input type="checkbox"/> Disagree |

- C-7** I am interested in improving my current physical ability to control when I urinate. ☐ Agree
☐ Disagree
- C-8** I am concerned about the embarrassment of having a prostate cancer screening exam. ☐ Agree
☐ Disagree
- C-9** I am interested in improving my physical ability to have sexual intercourse. ☐ Agree
☐ Disagree
- C-10** I am worried that I could die from prostate cancer. ☐ Agree
☐ Disagree

Part D. Background Information

This part has questions about your health history and other information about your background.

D-1 Do you have, or have you ever had, prostate cancer?

- ☐ Yes
- ☐ No
- ☐ Don't know

D-2 Have you ever been told by a doctor that you have an enlarged prostate? This is called benign prostatic hyperplasia or BPH.

- ☐ Yes
- ☐ No
- ☐ Don't know

D-3 Have you ever had a prostate ultrasound exam?

- ☐ Yes
- ☐ No
- ☐ Don't know

D-4 Have you ever had a prostate biopsy?

- ☐ Yes
- ☐ No
- ☐ Don't know

D-5 How many years of education have you completed?

- ☐ Less than 12 years
- ☐ 12 years
- ☐ More than 12 years

D-6 What is your race or ethnic background?

- ☐ White/Not-Hispanic
- ☐ Black or African American
- ☐ Hispanic/Latino
- ☐ Asian or Pacific Islander
- ☐ Native American/American Indian

D-7 What is your current marital situation? Are you . . .

- ☐ Married
☐ Widowed
☐ Divorced
☐ Separated
☐ Never married
☐ Living as married

D-8 What is your date of birth?

19
month *day* *year*

D-9 In what state or country were you born?

State (or country) _____

D-10 In what city or town were you born?

City _____

Thank you.

Please return the survey in the envelope provided with the survey. The envelope already has postage stamps. You can just drop it into a mailbox.

Ronald E. Myers, PhD
Thomas Jefferson University
Sheridan Building, Suite 403
125 South 9th Street
Philadelphia, PA 19107

**Follow-up Survey
on What You Think
About
Prostate Cancer
Screening**

Practice Name
&
Thomas Jefferson University

To _____

About the Survey

This survey is a follow-up to the one that you completed about six months ago. We want to learn what you think now about screening for prostate cancer. The survey will take about 10 to 15 minutes to complete. All of your answers are confidential. Your name will not be used in any reports about this survey.

How to Complete the Survey

For all of the items in this survey, please check only one response box for each item. If you are not sure, please check the response that is closest to your ideas.

How to Return the Survey

Please return the survey in the envelope that comes with the survey. The envelope is addressed to Dr. Ronald E. Myers at Thomas Jefferson University. It already has postage stamps. You can just drop it into a mailbox.

After the Survey

After you complete the survey, we also will review your medical record.

Part A. Ideas About Prostate Cancer

For each item, please check one response.

- A-1. Experts agree that men should be checked for prostate cancer. ☐ True
☐ False
- A-2. Doctors can tell if a prostate cancer is slow growing (not dangerous) or fast growing (dangerous). ☐ True
☐ False
- A-3. Being treated for prostate cancer can cause men to have problems holding their urine (incontinence). ☐ True
☐ False
- A-4. There is clear proof that being treated for prostate cancer saves lives. ☐ True
☐ False
- A-5. Being treated for prostate cancer can cause men to have problems holding an erection (impotence). ☐ True
☐ False

A-6. The doctor I see is likely to think I should go through prostate screening (with a rectal exam and PSA blood test).

- ☐ Strongly *agree*
- ☐ Sort of agree
- ☐ Sort of disagree
- ☐ Strongly *disagree*

A-7. Being treated for prostate cancer is likely to increase my chances of living a healthier life.

- ☐ Strongly *agree*
- ☐ Sort of agree
- ☐ Sort of disagree
- ☐ Strongly *disagree*

A-8. I think the benefits of prostate screening outweigh any difficulty I might have in going through the tests.

- ☐ Strongly *agree*
- ☐ Sort of agree
- ☐ Sort of disagree
- ☐ Strongly *disagree*

A-9. Being treated for prostate cancer is likely to increase my chances of living a longer life.

- ☐ Strongly *agree*
- ☐ Sort of agree
- ☐ Sort of disagree
- ☐ Strongly *disagree*

A-10. Having a prostate screening test makes sense to me.

- ☐ Strongly *agree*
- ☐ Sort of agree
- ☐ Sort of disagree
- ☐ Strongly *disagree*

A-11. I believe that going through prostate screening would help me to be healthy.

- ☐ Strongly *agree*
- ☐ Sort of agree
- ☐ Sort of disagree
- ☐ Strongly *disagree*

A-12. Men who go through prostate screening will have more problems than men who do *not* go through screening.

- ☐ Strongly *agree*
- ☐ Sort of agree
- ☐ Sort of disagree
- ☐ Strongly *disagree*

A-13. I think African American men are more likely to develop prostate cancer than white men.

- ☐ Strongly *agree*
- ☐ Sort of agree
- ☐ Sort of disagree
- ☐ Strongly *disagree*

A-14. I believe that when prostate cancer is found early, it can be cured.

- ☐ Strongly *agree*
- ☐ Sort of agree
- ☐ Sort of disagree
- ☐ Strongly *disagree*

A-15. I think that men who have a father or brother with prostate cancer are more likely to develop prostate cancer than men who do *not* have a father or brother with prostate cancer.

- ☐ Strongly *agree*
- ☐ Sort of agree
- ☐ Sort of disagree
- ☐ Strongly *disagree*

Part B.
Decision about Prostate Screening Exam

- B-1.** Did you discuss prostate screening with a doctor?
- ☐ No → → **Go to B-2.**
☐ Yes
-
-

What did the doctor recommend?

- ☐ Have the screening exam.
☐ Do **not** have the screening exam.
☐ The doctor made no recommendation.

- B-2.** What have you decided about having (or not having) a prostate screening exam in the future?
- ☐ I want to schedule an exam.
☐ I do **not** want to schedule an exam.
☐ I am not sure about scheduling an exam.
☐ I want to talk to the doctor about the exam.
☐ Other _____

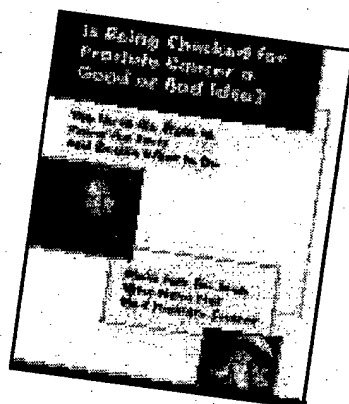
Write in response.

Part C. Booklet

About six months ago, we sent you a booklet about prostate cancer and early detection, called

Is Being Checked for Prostate Cancer a Good or Bad Idea?

The next group of questions are about that booklet.



C-1. Do you remember receiving a copy of this booklet shown above?

- ☐ Yes
☐ No → **Go to Part D.**

C-2. Did you read the booklet?

- ☐ Yes
☐ No → **Go to Part D.**

C-3. Did the information in the booklet help you to make a decision about having (or not having) a prostate screening exam.

- ☐ Yes
☐ No

C-4. Would you recommend the booklet to other men?

- ☐ Yes
☐ No
☐ Don't Know

Part D. Talk With Health Educator

About six months ago, a health educator from our office contacted you to discuss prostate cancer early detection.

The next group of questions are about talking with the health educator.

D-1. Do you remember talking with the health educator?

☐ Yes

☐ No → **Go to Part E.**

D-2. Did the information you talked about help you to make a decision about having a prostate screening exam?

☐ Yes

☐ No

D-3. Would you recommend the talk to other men?

☐ Yes

☐ No

☐ Don't Know

Part E. Health History

E-1. Do you have, or have you ever had, prostate cancer?

- ☐ Yes
- ☐ No
- ☐ Don't Know

E-2. Have you ever been told by a doctor that you have an enlarged prostate? This is called benign prostatic hyperplasia or BPH.

- ☐ Yes
- ☐ No
- ☐ Don't Know

E-3. Have you ever had a prostate ultrasound exam?

- ☐ Yes
- ☐ No
- ☐ Don't Know

E-4. Have you ever had a prostate biopsy?

- ☐ Yes
- ☐ No
- ☐ Don't Know

E-5. In the past 12 months,
have you had a rectal exam
as part of a prostate cancer
screening examination?

☐ No → **Go to E-6.**

☐ Yes

When was the exam done?

--	--	--	--

month year

In what physician's office?

Write in office name.

E-6. In the past 12 months, have
you had a prostate specific
antigen or PSA blood test
as part of a prostate cancer
screening examination?

☐ No → **Thank you.**

☐ Yes

When was the test done?

--	--	--	--

month year

In what physician's office?

Write in office name.

Thank you.

Please return the survey in the envelope provided with the survey. The envelope already has postage stamps. You can just drop it into a mailbox.

Ronald E. Myers, PhD
Thomas Jefferson University
Sheridan Building, Suite 403
125 South 9th Street
Philadelphia, PA 19107

PLEASE NOTE: This file is an example of a mailed endpoint survey that was sent to Enhanced Intervention group men. The Standard Intervention endpoint survey did not contain the section regarding the "Talk With A Health Educator".

Endpt. X

Chart Audit Form

Patient Name _____	Auditor _____
Address _____	Audit Date ____/____/____
Tel. No. _____	Practice _____
Patient Birthdate ____/____/____	
Patient Number _____	

Section A. Prostate Disease History

**A-1 Prostate Cancer,
Personal History**

- ☐ Yes ➡ ➡ ➡
☐ No
☐ Unknown

Date of diagnosis ____/____/____
 Stage at diagnosis _____
 Gleason score _____

**A-2 BPH,
Personal History**

- ☐ Yes ➡ ➡ ➡
☐ No
☐ Unknown

Date of diagnosis ____/____/____

**A-3 Prostatitis,
Personal History**

- ☐ Yes ➡ ➡ ➡
☐ No
☐ Unknown

Date of diagnosis ____/____/____

**A-4 Prostate Cancer,
Family History**

- ☐ Yes ➡ ➡ ➡
☐ No
☐ Unknown

Check all that apply

- ☐ Father
☐ Brother(s) ➡ ➡ Number of brothers _____
☐ Grandfather, maternal
☐ Grandfather, paternal
☐ Grandfather, unknown lineage
☐ Uncle(s), maternal ➡ ➡ No. of uncles _____
☐ Uncle(s), paternal ➡ ➡ No. of uncles _____
☐ Uncle(s), unknown lineage ➡ ➡ No. of uncles _____

Section B. Prostate Screening History

B-1. DRE

☐ Yes ➡ ➡ Number of DRE's _____ recorded in chart
☐ No

Most recent DRE

DRE date / ____ / ____ / ____ /
DRE result ☐ Normal
☐ Abnormal (specify) _____
DRE reason ☐ Screening
☐ Symptoms
☐ Unknown
☐ Other (specify) _____

B-2. PSA

☐ Yes ➡ ➡ Number of PSA's _____ recorded in chart
☐ No

Most recent PSA

PSA date / ____ / ____ / ____ /
PSA result _____ ng/ mg
PSA reason ☐ Screening
☐ Symptoms
☐ Unknown
☐ Other (specify) _____

B-3. Urology Referral

☐ Yes ➡ ➡ Number of referral's _____ recorded in chart
☐ No

Most recent referral

Referral date / ____ / ____ / ____ /
Referral reason ☐ Abnormal DRE
☐ Abnormal PSA
☐ Unknown
☐ Other (specify) _____
Urologist name _____
Report in chart ☐ Yes ☐ No

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B-4. TRUS

☐ Yes ➡ ➡ Number of TRUS's _____ recorded in chart
☐ No

Most recent TRUS

TRUS date	/ ____ / ____ / ____ /
TRUS result	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal (specify) _____
TRUS reason	<input type="checkbox"/> Follow-up Abnormal DRE <input type="checkbox"/> Follow-up Abnormal PSA <input type="checkbox"/> Unknown <input type="checkbox"/> Other (specify) _____
Urologist name	_____
Report in chart	<input type="checkbox"/> Yes <input type="checkbox"/> No

B-5. Biopsy

☐ Yes ➡ ➡ Number of biopsies _____ recorded in chart
☐ No

Most recent biopsy

Biopsy date	/ ____ / ____ / ____ /
Biopsy result	<input type="checkbox"/> Normal
Biopsy reason	<input type="checkbox"/> Abnormal (specify) _____ <input type="checkbox"/> Follow-up Abnormal DRE <input type="checkbox"/> Follow-up Abnormal PSA <input type="checkbox"/> Unknown <input type="checkbox"/> Other (specify) _____
Urologist Name	_____
Report in chart	<input type="checkbox"/> Yes <input type="checkbox"/> No

Section C. Comorbidities by System

C-1 Cardiovascular

A... Past Myocardial Infarction

☐ Yes ➔ ➔
☐ No

Date of most recent event / ____ / ____ / ____ /

B... Congestive Heart Failure

☐ Yes ➔ ➔
☐ No

Date of most recent acute CHD episode or a CHF-related hospitalization / ____ / ____ / ____ /

C... Peripheral Vascular Disease

☐ Yes ➔ ➔
☐ No

☐ Intermittent Claudication

☐ Other _____

D... Atherosclerosis

☐ Yes
☐ No

E... Other

☐ Yes ➔ ➔
☐ No

(specify) _____

C-2 Respiratory

A... Dyspnea

☐ Yes ➔ ➔
☐ N

Date of most recent episode / ____ / ____ / ____ /

B... Asthma

☐ Yes ➔ ➔
☐ No

Date of most recent severe episode / ____ / ____ / ____ /

C... COPD

☐ Yes
☐ No

NOTE: Include chronic bronchitis and chronic emphysema

D... Other respiratory condition

☐ Yes ➔ ➔
☐ No

Specify _____

C-3 Cerebral

A... Stroke

☐ Yes ➔ ➔
☐ No

Date of most recent stroke / ____ / ____ / ____ /

Any indication of residual impairments (e.g., paralysis)?

☐ Yes ☐ No

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B... Transient Ischemic Attack(s)

☐ Yes ➔ ➔
☐ No

Date of most recent TIA / ____ / ____ / ____ /

C... Dementia

☐ Yes ➔ ➔
☐ No

☐ Alzheimer's Disease

☐ Other _____

D... Other Cerebral condition

☐ Yes ➔ ➔
☐ No

Specify _____

C-4 Endocrine

A... Diabetes

☐ Yes ➔ ➔
☐ No

Date of diagnosis / ____ / ____ / ____ /

Any indication of diabetes-associated retinopathy, neuropathy, or nephropathy?

☐ Yes ☐ No

Any indication of any past diabetes-associated hospitalizations?

☐ Yes ☐ No

B... Other endocrine condition

☐ Yes ➔ ➔
☐ No

Specify _____

C-5 Renal

A... Chronic Renal Failure

Include renal insufficiency, uremia, dialysis dependency, past renal transplant or removal of one kidney or non-functioning kidney.

☐ Yes ➔ ➔
☐ No

Any indication of dialysis dependency or past renal transplantation?

☐ Yes ☐ No

B... Other renal condition

☐ Yes ➔ ➔
☐ No

Specify _____

C-6 Hepatic

A... Cirrhosis

☐ Yes ➔ ➔
☐ No

Any indication of portal hypertension?

☐ Yes ☐ No

B... Chronic Hepatitis

☐ Yes ➔ ➔
☐ No

Specify type _____

C... Esophageal Varices

☐ Yes
☐ No

Jefferson Internal Medicine Associates Prostate Study

D... Other hepatic condition

☐ Yes ➔ ➔
☐ No

Specify _____

C-7 Gastrointestinal

A... Peptic Ulcer

☐ Yes ➔ ➔
☐ No

Any indication of bleeding that required transfusion?

☐ Yes ☐ No

B... Other GI condition

☐ Yes ➔ ➔
☐ No

Specify _____

C-8 Neoplastic

A... Solid Tumor(s)

☐ Yes ➔ ➔
☐ No

Date of initial treatment /____/____/____/

Specify solid tumor _____

Any indication that this tumor is metastatic?

☐ Yes ☐ No

B... Lymphoma or Leukemia

☐ Yes ➔ ➔
☐ No

Date of initial treatment /____/____/____/

C... Malignant Melanoma

☐ Yes ➔ ➔
☐ No

Date of initial treatment /____/____/____/

D... Other neoplastic condition

☐ Yes ➔ ➔
☐ No

Date of initial treatment /____/____/____/

Specify _____

C-9 HIV and AIDS

A... HIV seropositive

☐ Yes ➔ ➔
☐ No

Did initial treatment occur within 5 years of this audit?

☐ Yes ☐ No

B... AIDS diagnosis

☐ Yes ➔ ➔
☐ No

Did initial treatment occur within 5 years of this audit?

☐ Yes ☐ No

C-10 Sexually transmitted disease

Sexually transmitted disease

☐ Yes ➔ ➔
☐ No

Specify _____

Chart Audit Form

Patient Name _____	Auditor _____
Address _____ _____	Audit Date / ____ / ____ / ____ /
Tel. No. — — .	
Patient Birthdate / ____ / ____ / ____ /	Practice _____
Patient Number _____	_____

Section A. Prostate Disease History

**A-1 Prostate Cancer,
Personal History**

- ☐ Yes \ \ \
☐ No
☐ Unknown

Date of diagnosis / ____ / ____ / ____ /
 Stage at diagnosis _____
 Gleason score _____

**A-2 BPH,
Personal History**

- ☐ Yes \ \ \
☐ No
☐ Unknown

Date of diagnosis / ____ / ____ / ____ /

**A-3 Prostatitis,
Personal History**

- ☐ Yes \ \ \
☐ No
☐ Unknown

Date of diagnosis / ____ / ____ / ____ /

**A-4 Prostate Cancer,
Family History**

- ☐ Yes \ \ \
☐ No
☐ Unknown

Check all that apply

- ☐ Father
☐ Brother(s) \ \ Number of brothers _____
☐ Grandfather, maternal
☐ Grandfather, paternal
☐ Grandfather, unknown lineage
☐ Uncle(s), maternal \ \ No. of uncles _____
☐ Uncle(s), paternal \ \ No. of uncles _____

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☐ Uncle(s), unknown lineage \ \ No. of uncles _____

Section B. Prostate Screening History

B-1. DRE

☐ Yes \ \ Number of DRE's _____ recorded in chart

☐ No

Most recent DRE

DRE date / ____ / ____ / ____ /

DRE result ☐ Normal

☐ Abnormal (specify) _____

DRE reason ☐ Screening

☐ Symptoms

☐ Unknown

☐ Other (specify) _____

B-2. PSA

☐ Yes \ \ Number of PSA's _____ recorded in chart

☐ No

Most recent PSA

PSA date / ____ / ____ / ____ /

PSA result _____ ng/ mg

PSA reason ☐ Screening

☐ Symptoms

☐ Unknown

☐ Other (specify) _____

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B-3. Urology Referral

☐ Yes \ \ Number of referral's _____ recorded in chart
☐ No

Most recent referral

Referral date / ____ / ____ / ____ /

Referral reason ☐ Abnormal DRE
☐ Abnormal PSA
☐ Unknown
☐ Other (specify) _____

Urologist name _____

Report in chart ☐ Yes ☐ No

B-4. TRUS

☐ Yes \ \ Number of TRUS's _____ recorded in chart
☐ No

Most recent TRUS

TRUS date / ____ / ____ / ____ /

TRUS result ☐ Normal
☐ Abnormal (specify) _____

TRUS reason ☐ Follow-up Abnormal DRE
☐ Follow-up Abnormal PSA
☐ Unknown
☐ Other (specify) _____

Urologist name _____

Report in chart ☐ Yes ☐ No

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B-5. Biopsy

☐ Yes \ \ Number of biopsies _____ recorded in chart
☐ No

Most recent biopsy

Biopsy date	/ ____ / ____ / ____ /
Biopsy result	<input type="checkbox"/> Normal
Biopsy reason	<input type="checkbox"/> Abnormal (specify) _____
	<input type="checkbox"/> Follow-up Abnormal DRE
	<input type="checkbox"/> Follow-up Abnormal PSA
	<input type="checkbox"/> Unknown
	<input type="checkbox"/> Other (specify) _____
Urologist Name	_____
Report in chart	<input type="checkbox"/> Yes <input type="checkbox"/> No

Section C. Comorbidities by System

C-1 Cardiovascular

A... Past Myocardial Infarction

- ☐ Yes () ()
☐ No

Date of most recent event / ____ / ____ / ____ /

B... Congestive Heart Failure

- ☐ Yes () ()
☐ No

Date of most recent acute CHD episode or a CHF-related hospitalization / ____ / ____ / ____ /

C... Peripheral Vascular Disease

- ☐ Yes () ()
☐ No

☐ Intermittent Claudication

☐ Other _____

D... Atherosclerosis

- ☐ Yes
☐ No

E... Other

- ☐ Yes () ()
☐ No

(specify) _____

C-2 Respiratory

A... Dyspnea

- ☐ Yes () ()
☐ N

Date of most recent episode / ____ / ____ / ____ /

B... Asthma

- ☐ Yes () ()
☐ No

Date of most recent severe episode / ____ / ____ / ____ /

C... COPD

- ☐ Yes
☐ No

NOTE: Include chronic bronchitis and chronic emphysema

D... Other respiratory condition

- ☐ Yes () ()
☐ No

Specify _____

C-3 Cerebral

A... Stroke

- ☐ Yes () ()
☐ No

Date of most recent stroke / ____ / ____ / ____ /

Any indication of residual impairments (e.g., paralysis)?

☐ Yes ☐ No

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B... Transient Ischemic Attack(s)

☐ Yes ()
☐ No

Date of most recent TIA / ____ / ____ / ____ /

C... Dementia

☐ Yes ()
☐ No

☐ Alzheimer's Disease

☐ Other _____

D... Other Cerebral condition

☐ Yes ()
☐ No

Specify _____

C-4 Endocrine

A... Diabetes

☐ Yes ()
☐ No

Date of diagnosis / ____ / ____ / ____ /

Any indication of diabetes-associated retinopathy, neuropathy, or nephropathy?

☐ Yes ☐ No

Any indication of any past diabetes-associated hospitalizations?

☐ Yes ☐ No

B... Other endocrine condition

☐ Yes ()
☐ No

Specify _____

C-5 Renal

A... Chronic Renal Failure

Include renal insufficiency, uremia, dialysis dependency, past renal transplant or removal of one kidney or non-functioning kidney.

☐ Yes ()
☐ No

Any indication of dialysis dependency or past renal transplantation?

☐ Yes ☐ No

B... Other renal condition

☐ Yes ()
☐ No

Specify _____

C-6 Hepatic

A... Cirrhosis

☐ Yes ()
☐ No

Any indication of portal hypertension?

☐ Yes ☐ No

B... Chronic Hepatitis

☐ Yes ()
☐ No

Specify type _____

C... Esophageal Varices

☐ Yes

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☐ No

D... Other hepatic condition

☐ Yes

☐ No

Specify _____

C-7 Gastrointestinal

A... Peptic Ulcer

☐ Yes

☐ No

Any indication of bleeding that required transfusion?

☐ Yes

☐ No

B... Other GI condition

☐ Yes

☐ No

Specify _____

C-8 Neoplastic

A... Solid Tumor(s)

☐ Yes

☐ No

Date of initial treatment / ____/____/____/

Specify solid tumor _____

Any indication that this tumor is metastatic?

☐ Yes

☐ No

B... Lymphoma or Leukemia

☐ Yes

☐ No

Date of initial treatment / ____/____/____/

C... Malignant Melanoma

☐ Yes

☐ No

Date of initial treatment / ____/____/____/

D... Other neoplastic condition

☐ Yes

☐ No

Date of initial treatment / ____/____/____/

Specify _____

C-9 HIV and AIDS

A... HIV seropositive

☐ Yes

☐ No

Did initial treatment occur within 5 years of this audit?

☐ Yes

☐ No

B... AIDS diagnosis

☐ Yes

☐ No

Did initial treatment occur within 5 years of this audit?

☐ Yes

☐ No

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C-10 Sexually transmitted disease

Sexually transmitted disease

☐ Yes ()

Specify _____

☐ No
